



Clinical trial results:

Three-, Five-, and Ten-Year Data on the Long-Term Immunogenicity of Tetanus and Diphtheria Toxoids Adsorbed Combined with Component Pertussis Vaccine and Inactivated Poliomyelitis Vaccine (TdcP-IPV) in Adolescents 11–14 Years of Age

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2015-005196-24 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 04 June 2009 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v1 (current) |
| This version publication date | 16 April 2016 |
| First version publication date | 16 April 2016 |

Trial information

Trial identification

| | |
|-----------------------|-----------|
| Sponsor protocol code | TD9809-LT |
|-----------------------|-----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02040636 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Sanofi Pasteur Limited |
| Sponsor organisation address | 1755 Steeles Ave. West, Toronto, Canada, M2R 3T4 |
| Public contact | Clinical Team Leader, Sanofi Pasteur Limited, 1 416-667-2273, Miggi.Tomovici@sanofipasteur.com |
| Scientific contact | Clinical Team Leader, Sanofi Pasteur Limited, 1 416-667-2273, Miggi.Tomovici@sanofipasteur.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|--------------|
| Analysis stage | Final |
| Date of interim/final analysis | 04 June 2009 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|--------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 04 June 2009 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

1. The objective of this study was to describe the antibody levels for tetanus, diphtheria, pertussis and polio at 3 years, 5 years, and 10 years after vaccination with TdcP-IPV Vaccine.

Protection of trial subjects:

Subjects were vaccinated in a previous study, Td9809. No vaccination was administered as part of this long-term immunogenicity follow-up study.

Background therapy:

In Td9809, subjects were randomized to receive either Tetanus and Diphtheria Toxoids Adsorbed and Component Pertussis Vaccine Combined with Inactivated Poliomyelitis Vaccine (TdcP-IPV) followed by Hepatitis B vaccine one month later or TdcP-IPV vaccine and Hepatitis B vaccine concomitantly. For the long-term follow-up study, subjects in both groups were recalled for serology at 3, 5, and 10 years.

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 23 January 2002 |
| 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 | Canada: 277 |
| Worldwide total number of subjects | 277 |
| 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) | 0 |
| Children (2-11 years) | 101 |
| Adolescents (12-17 years) | 176 |

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

Subject disposition

Recruitment

Recruitment details:

The study subjects were enrolled from 23 January 2002 to 04 June 2009 at 1 clinic center in Canada.

Pre-assignment

Screening details:

A total of 277 subjects who met all inclusion and none of the exclusion criteria were enrolled in the long-term immunogenicity study.

Period 1

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

Blinding implementation details:

Not applicable

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|-------------------------------|
| Arm title | Group 1: Tdcp-IPV/Hepatitis B |
|------------------|-------------------------------|

Arm description:

Subjects received TdcP-IPV at month 0 and Hepatitis B at months 1, 2, and 7.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Tetanus and Diphtheria Toxoids Adsorbed and Component Pertussis Vaccine with Inactivated Poliovirus (TdcP-IPV Vaccine) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

0.5 mL, intramuscular, 1 injection at Month 0.

| | |
|--|--------------------------------------|
| Investigational medicinal product name | Hepatitis B Vaccine (Recombivax HB®) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

0.5 mL, intramuscular, 1 injection each at Months 1, 2, and 7.

| | |
|------------------|-----------------------------------|
| Arm title | Group 2: Tdcp-IPV and Hepatitis B |
|------------------|-----------------------------------|

Arm description:

Subjects received TdcP-IPV and Hepatitis B at Month 0, Hepatitis B at months 1 and 6.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Tetanus and Diphtheria Toxoids Adsorbed and Component Pertussis Vaccine with Inactivated Poliovirus (TdcP-IPV Vaccine) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

0.5 mL, intramuscular, 1 injection at Month 0.

| | |
|--|--------------------------------------|
| Investigational medicinal product name | Hepatitis B Vaccine (Recombivax HB®) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

0.5 mL, intramuscular, 1 injection at Month 0 concurrent with TdcP-IPV and 1 injection each at Months 1 and 6.

| Number of subjects in period 1 | Group 1: Tdcp-IPV/Hepatitis B | Group 2: Tdcp-IPV and Hepatitis B |
|---------------------------------------|-------------------------------|-----------------------------------|
| Started | 144 | 133 |
| Completed | 91 | 83 |
| Not completed | 53 | 50 |
| Lost to follow-up | 53 | 50 |

Baseline characteristics

Reporting groups

| | |
|---|-----------------------------------|
| Reporting group title | Group 1: Tdcp-IPV/Hepatitis B |
| Reporting group description: | |
| Subjects received TdcP-IPV at month 0 and Hepatitis B at months 1, 2, and 7. | |
| Reporting group title | Group 2: Tdcp-IPV and Hepatitis B |
| Reporting group description: | |
| Subjects received TdcP-IPV and Hepatitis B at Month 0, Hepatitis B at months 1 and 6. | |

| Reporting group values | Group 1: Tdcp-IPV/Hepatitis B | Group 2: Tdcp-IPV and Hepatitis B | Total |
|--|-------------------------------|-----------------------------------|-------|
| Number of subjects | 144 | 133 | 277 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 48 | 53 | 101 |
| Adolescents (12-17 years) | 96 | 80 | 176 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 12.43 | 12.43 | |
| standard deviation | ± 0.83 | ± 0.95 | - |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 75 | 60 | 135 |
| Male | 69 | 73 | 142 |

End points

End points reporting groups

| | |
|---|-----------------------------------|
| Reporting group title | Group 1: Tdcp-IPV/Hepatitis B |
| Reporting group description: | |
| Subjects received TdcP-IPV at month 0 and Hepatitis B at months 1, 2, and 7. | |
| Reporting group title | Group 2: Tdcp-IPV and Hepatitis B |
| Reporting group description: | |
| Subjects received TdcP-IPV and Hepatitis B at Month 0, Hepatitis B at months 1 and 6. | |

Primary: Percentage of Subjects with Seroprotection to Tetanus and Diphtheria Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently

| | |
|---|---|
| End point title | Percentage of Subjects with Seroprotection to Tetanus and Diphtheria Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently ^[1] |
| End point description: | |
| Anti-Diphtheria antibody responses were measured using a micrometabolic inhibition test. Anti-Tetanus antibody responses were measured using an enzyme-linked immunosorbent assay (ELISA). Seroprotection was defined as post-vaccination antibody titers ≥ 0.01 IU/mL for Diphtheria and ≥ 0.01 EU/mL for Tetanus. | |
| End point type | Primary |
| End point timeframe: | |
| Day 0 (pre-vaccination) and 1 month and 3, 5, and 10 years 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: Descriptive analyses were performed, based on the vaccine groups from the primary series for the long term follow-up period.

| End point values | Group 1: Tdcp-IPV/Hepatitis B | Group 2: Tdcp-IPV and Hepatitis B | | |
|---------------------------------------|-------------------------------|-----------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 144 | 132 | | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Diphtheria; Pre-vaccination | 95.8 | 100 | | |
| Diphtheria; 1 month Post-vaccination | 100 | 100 | | |
| Diphtheria; 3 years Post-vaccination | 100 | 98 | | |
| Diphtheria; 5 years Post-vaccination | 96.4 | 100 | | |
| Diphtheria; 10 years Post-vaccination | 97.7 | 100 | | |
| Tetanus; Pre-vaccination | 100 | 100 | | |
| Tetanus; 1 month Post-vaccination | 100 | 100 | | |
| Tetanus; 3 years Post-vaccination | 100 | 100 | | |
| Tetanus; 5 years Post-vaccination | 100 | 100 | | |
| Tetanus; 10 years Post-vaccination | 100 | 100 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects with Seroprotection to Tetanus and Diphtheria Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently

| | |
|-----------------|--|
| End point title | Percentage of Subjects with Seroprotection to Tetanus and Diphtheria Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently |
|-----------------|--|

End point description:

Anti-Diphtheria antibody responses were measured using a micrometabolic inhibition test. Anti-Tetanus antibody responses were measured using an enzyme-linked immunosorbent assay (ELISA). Seroprotection was defined as post-vaccination antibody titers ≥ 0.1 IU/mL for Diphtheria and ≥ 0.1 EU/mL for Tetanus.

| | |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

Day 0 (pre-vaccination) and 1 month and 3, 5, and 10 years post-vaccination

| End point values | Group 1: TdcP-IPV/Hepatitis B | Group 2: TdcP-IPV and Hepatitis B | | |
|---------------------------------------|-------------------------------|-----------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 144 | 132 | | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Diphtheria; Pre-vaccination | 63.2 | 67.4 | | |
| Diphtheria; 1 month Post-vaccination | 98.6 | 100 | | |
| Diphtheria; 3 years Post-vaccination | 83.6 | 82 | | |
| Diphtheria; 5 years Post-vaccination | 49.1 | 47.9 | | |
| Diphtheria; 10 years Post-vaccination | 57 | 54.3 | | |
| Tetanus; Pre-vaccination | 99.3 | 100 | | |
| Tetanus; 1 month Post-vaccination | 100 | 100 | | |
| Tetanus; 3 years Post-vaccination | 100 | 100 | | |
| Tetanus; 5 years Post-vaccination | 100 | 99 | | |
| Tetanus; 10 years Post-vaccination | 100 | 97.1 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Summary of Geometric Mean Titers of Antibodies for Diphtheria and Tetanus Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently

| | |
|-----------------|---|
| End point title | Summary of Geometric Mean Titers of Antibodies for Diphtheria and Tetanus Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently |
|-----------------|---|

End point description:

Anti-Diphtheria antibody responses were measured using a micrometabolic inhibition test. Anti-Tetanus antibody responses were measured using an enzyme-linked immunosorbent assay (ELISA).

| | |
|---|---------------------|
| End point type | Other pre-specified |
| End point timeframe: | |
| Day 0 (pre-vaccination) and 1 month and 3, 5, and 10 years post-vaccination | |

| End point values | Group 1: Tdcp-IPV/Hepatitis B | Group 2: Tdcp-IPV and Hepatitis B | | |
|--|-------------------------------|-----------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 144 | 132 | | |
| Units: Titers (1/dil) | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Diphtheria; Pre-vaccination | 0.15 (0.12 to 0.19) | 0.2 (0.16 to 0.25) | | |
| Diphtheria; 1 month Post-vaccination | 2.56 (2.11 to 3.11) | 2.95 (2.48 to 3.5) | | |
| Diphtheria; 3 years Post-vaccination | 0.26 (0.21 to 0.32) | 0.29 (0.22 to 0.37) | | |
| Diphtheria; 5 years Post-vaccination | 0.11 (0.09 to 0.13) | 0.11 (0.09 to 0.14) | | |
| Diphtheria; 10 years Post-vaccination | 0.17 (0.13 to 0.23) | 0.15 (0.12 to 0.2) | | |
| Tetanus; Pre-vaccination | 0.82 (0.71 to 0.94) | 0.87 (0.75 to 1.01) | | |
| Tetanus; 1 month Post-vaccination | 19.54 (16.91 to 22.56) | 17.4 (14.88 to 20.35) | | |
| Tetanus; 3 years Post-vaccination | 2.29 (1.99 to 2.64) | 2.24 (1.9 to 2.64) | | |
| Tetanus; 5 years Post-vaccination | 1.4 (1.16 to 1.68) | 1.48 (1.22 to 1.81) | | |
| Tetanus; 10 years Post-vaccination | 0.95 (0.76 to 1.2) | 1.05 (0.83 to 1.34) | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Summary of Geometric Mean Titers of Antibodies for Pertussis Following Vaccination with Either Tdcp-IPV or Tdcp-IPV and Hepatitis B Vaccine Given Concurrently

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|---|--|
| End point title | Summary of Geometric Mean Titers of Antibodies for Pertussis Following Vaccination with Either Tdcp-IPV or Tdcp-IPV and Hepatitis B Vaccine Given Concurrently |
| End point description: | |
| Anti-Pertussis (Pertussis toxoid, Filamentous hemagglutinin, Fimbriae types 2 and 3, and Pertactin) antibody responses were measured using an indirect enzyme-linked immunosorbent assay (ELISA). | |
| End point type | Other pre-specified |
| End point timeframe: | |
| Day 0 (pre-vaccination) and 1 month and 3, 5, and 10 years post-vaccination | |

| End point values | Group 1: Tdcp-IPV/Hepatitis B | Group 2: Tdcp-IPV and Hepatitis B | | |
|--|-------------------------------|-----------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 144 | 132 | | |
| Units: Titers (1/dil) | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Pertussis toxoid; Pre-vaccination | 17.09 (13.69 to 21.35) | 16.43 (12.91 to 20.92) | | |
| Pertussis toxoid; 1 month Post-vaccination | 267.87 (224.32 to 319.88) | 222.63 (186.1 to 266.32) | | |
| Pertussis toxoid; 3 years Post-vaccination | 61.06 (49.44 to 75.4) | 48.91 (39.25 to 60.95) | | |
| Pertussis toxoid; 5 years Post-vaccination | 47.99 (39.54 to 58.23) | 42.11 (33.35 to 53.16) | | |
| Pertussis toxoid; 10 years Post-vaccination | 10.73 (8.24 to 13.97) | 14.64 (10.73 to 19.98) | | |
| Filamentous hemagglutinin; Pre-vaccination | 33.53 (27.87 to 40.35) | 39.93 (32.15 to 49.59) | | |
| Filamentous hemagglutinin;1 month Post-vaccination | 295 (255.11 to 341.13) | 290.22 (252.95 to 332.97) | | |
| Filamentous hemagglutinin;3 years Post-vaccination | 64.95 (54.19 to 77.85) | 59.77 (49.88 to 71.62) | | |
| Filamentous hemagglutinin;5 years Post-vaccination | 56.9 (47.61 to 68.01) | 55.58 (46.51 to 66.42) | | |
| Filamentous hemagglutinin;10 year Post-vaccination | 33.3 (27.02 to 41.04) | 36.9 (29.34 to 46.41) | | |
| Pertactin; Pre-vaccination | 10.49 (8.31 to 13.23) | 13.36 (10.22 to 17.47) | | |
| Pertactin; 1 month Post-vaccination | 277.03 (220.45 to 348.13) | 240.45 (196.47 to 294.27) | | |
| Pertactin; 3 years Post-vaccination | 62.38 (49.04 to 79.34) | 63.74 (51.23 to 79.29) | | |
| Pertactin; 5 years Post-vaccination | 55.42 (43.57 to 70.49) | 62.5 (49.7 to 78.6) | | |
| Pertactin; 10 years Post-vaccination | 26.66 (20.65 to 34.41) | 36.96 (28.73 to 47.54) | | |
| Fimbriae; Pre-vaccination | 53.29 (42.27 to 67.2) | 62.36 (49.99 to 77.78) | | |
| Fimbriae; 1 month Post-vaccination | 1414.97 (1166.02 to 1717.06) | 1383.72 (1183.05 to 1618.43) | | |
| Fimbriae; 3 years Post-vaccination | 286.41 (237.06 to 346.02) | 266.46 (219.76 to 323.09) | | |
| Fimbriae; 5 years Post-vaccination | 199.91 (166.25 to 240.38) | 213.46 (178.04 to 255.93) | | |
| Fimbriae; 10 years Post-vaccination | 113.09 (92.99 to 137.54) | 122.1 (99.5 to 149.82) | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects with Seropositivity to Pertussis Antigens Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently

| | |
|-----------------|--|
| End point title | Percentage of Subjects with Seropositivity to Pertussis Antigens Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently |
|-----------------|--|

End point description:

Anti-Pertussis (Pertussis toxoid, Filamentous hemagglutinin, Fimbriae types 2 and 3, and Pertactin) antibody responses were measured using an indirect enzyme-linked immunosorbent assay (ELISA). Seropositivity rates, defined as the percentage of subjects with post-vaccination titers \geq lower limit of quantitation.

| | |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

Day 0 (pre-vaccination) and 1 month and 3, 5, and 10 years post-vaccination

| End point values | Group 1: Tdcp-IPV/Hepatitis B | Group 2: Tdcp-IPV and Hepatitis B | | |
|---|-------------------------------|-----------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 144 | 132 | | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Pertussis toxoid; Pre-vaccination | 84 | 79.5 | | |
| Pertussis toxoid; 1 month Post-vaccination | 100 | 100 | | |
| Pertussis toxoid; 3 years Post-vaccination | 96.4 | 96.2 | | |
| Pertussis toxoid; 5 years Post-vaccination | 98.3 | 94.2 | | |
| Pertussis toxoid; 10 years Post-vaccination | 71.6 | 76.9 | | |
| Filamentous hemagglutinin; Pre-vaccination | 99.3 | 98.5 | | |
| Filamentous hemagglutinin; 1 month Post-vaccination | 100 | 100 | | |
| Filamentous hemagglutinin; 3 years Post-vaccination | 100 | 100 | | |
| Filamentous hemagglutinin; 5 years Post-vaccination | 100 | 100 | | |
| Filamentous hemagglutinin; 10 year Post-vaccination | 98.9 | 97.5 | | |
| Pertactin; Pre-vaccination | 79.9 | 81.8 | | |
| Pertactin; 1 month Post-vaccination | 100 | 100 | | |
| Pertactin; 3 years Post-vaccination | 99.1 | 100 | | |

| | | | | |
|--------------------------------------|------|------|--|--|
| Pertactin; 5 years Post-vaccination | 98.3 | 99 | | |
| Pertactin; 10 years Post-vaccination | 95.6 | 97.5 | | |
| Fimbriae; Pre-vaccination | 79 | 86.3 | | |
| Fimbriae; 1 month Post-vaccination | 100 | 100 | | |
| Fimbriae; 3 years Post-vaccination | 99.1 | 99 | | |
| Fimbriae; 5 years Post-vaccination | 100 | 98.1 | | |
| Fimbriae; 10 years Post-vaccination | 96.7 | 97.5 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects with Seroprotection to Poliovirus Antigens Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently

| | |
|-----------------|---|
| End point title | Percentage of Subjects with Seroprotection to Poliovirus Antigens Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently |
|-----------------|---|

End point description:

Anti-poliovirus types 1, 2, and 3 titers were measured by a neutralization assay. Seroprotection was defined as antibody titers \geq 1:8 dilution.

| | |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

Day 0 (pre-vaccination) and 1 month and 3, 5, and 10 years post-vaccination

| End point values | Group 1: Tdcp-IPV/Hepatitis B | Group 2: Tdcp-IPV and Hepatitis B | | |
|---|-------------------------------|-----------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 144 | 132 | | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Poliovirus 1; Pre-vaccination | 97.2 | 98.5 | | |
| Poliovirus 1; 1 month Post-vaccination | 100 | 100 | | |
| Poliovirus 1; 3 years Post-vaccination | 100 | 100 | | |
| Poliovirus 1; 5 years Post-vaccination | 100 | 100 | | |
| Poliovirus 1; 10 years Post-vaccination | 100 | 100 | | |
| Poliovirus 2; Pre-vaccination | 100 | 100 | | |
| Poliovirus 2; 1 month Post-vaccination | 100 | 100 | | |
| Poliovirus 2; 3 years Post-vaccination | 100 | 100 | | |
| Poliovirus 2; 5 years Post-vaccination | 100 | 100 | | |
| Poliovirus 2; 10 years Post-vaccination | 100 | 100 | | |
| Poliovirus 3; Pre-vaccination | 95.1 | 95.5 | | |
| Poliovirus 3; 1 month Post-vaccination | 100 | 100 | | |
| Poliovirus 3; 3 years Post-vaccination | 100 | 100 | | |
| Poliovirus 3; 5 years Post-vaccination | 100 | 100 | | |
| Poliovirus 3; 10 years Post-vaccination | 100 | 100 | | |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Summary of Geometric Mean Titers of Poliovirus Antibodies Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently

| | |
|------------------------|---|
| End point title | Summary of Geometric Mean Titers of Poliovirus Antibodies Following Vaccination with Either TdcP-IPV or TdcP-IPV and Hepatitis B Vaccine Given Concurrently |
| End point description: | Anti-poliovirus types 1, 2, and 3 titers were measured by a neutralization assay. |
| End point type | Other pre-specified |
| End point timeframe: | Day 0 (pre-vaccination) and 1 month and 3, 5, and 10 years post-vaccination |

| End point values | Group 1: Tdcp-IPV/Hepatitis B | Group 2: Tdcp-IPV and Hepatitis B | | |
|--|---------------------------------|-----------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 144 | 132 | | |
| Units: Titers (1/dil) | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Poliovirus 1; Pre-vaccination | 134.96 (102.43 to 177.82) | 149.05 (111.01 to 200.14) | | |
| Poliovirus 1; 1 month Post-vaccination | 65216.88 (49464.4 to 85985.9) | 38157.97 (29955.97 to 48605.7) | | |
| Poliovirus 1; 3 years Post-vaccination | 3720.46 (2875.49 to 4813.73) | 2751.55 (2082.42 to 3635.68) | | |
| Poliovirus 1; 5 years Post-vaccination | 993.08 (809.3 to 1218.6) | 858.5 (702.21 to 1049.56) | | |
| Poliovirus 1; 10 years Post-vaccination | 883.71 (701.3 to 1113.57) | 873.49 (703.25 to 1084.93) | | |
| Poliovirus 2; Pre-vaccination | 271.22 (216.94 to 339.08) | 306.04 (251.16 to 372.92) | | |
| Poliovirus 2; 1 month Post-vaccination | 152485.2 (115163.6 to 201901.7) | 90280.15 (71624.22 to 113795.3) | | |
| Poliovirus 2; 3 years Post-vaccination | 10756.89 (8104.16 to 14277.94) | 8928.76 (6640.15 to 12006.17) | | |

| | | | | |
|---|-------------------------------------|-------------------------------------|--|--|
| Poliovirus 2; 5 years Post-vaccination | 2296.33 (1827.35 to 2885.67) | 2168.22 (1749.3 to 2687.46) | | |
| Poliovirus 2; 10 years Post-vaccination | 1429.53 (1111.05 to 1839.31) | 1277.51 (988.26 to 1651.42) | | |
| Poliovirus 3; Pre-vaccination | 48.64 (38.32 to 61.75) | 45.97 (36.95 to 57.2) | | |
| Poliovirus 3; 1 month Post-vaccination | 230898.8 (174414 to 305676.4) | 136695.4 (104880.7 to 178161) | | |
| Poliovirus 3; 3 years Post-vaccination | 5827.34 (4431.04 to 7663.63) | 5411.71 (4021.19 to 7283.07) | | |
| Poliovirus 3; 5 years Post-vaccination | 846.01 (664.4 to 1077.27) | 825.26 (641.97 to 1060.89) | | |
| Poliovirus 3; 10 years Post-vaccination | 758.31 (584.66 to 983.55) | 782.8 (583.55 to 1050.08) | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

This was a long-term immunogenicity follow-up study of subjects who participated in a previous study, Td9809. No vaccines were administered in this study and adverse event data were also not collected.

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|----|
| Dictionary version | 10 |
|--------------------|----|

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: This was a long-term immunogenicity follow-up study of subjects who participated in a previous study, Td9809. No vaccines were administered in this study and adverse event data were also not collected

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------|--|
| 23 May 2001 | Details regarding the planned long-term follow-up serology studies were included which also involved the collection of additional blood samples at 1, 3, 5, and 10 years post-vaccination. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/25540274>