



Clinical trial results:

A phase III, randomised, controlled, single-blind study to evaluate the safety and immunogenicity of GlaxoSmithKline (GSK) Biologicals' HPV-16/18 L1 VLP AS04 vaccine administered according to a 2-dose schedule (0, 6 month) in 4-6 years old healthy female children.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2011-005604-15 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v1 |
| This version publication date | 01 April 2017 |
| First version publication date | 01 April 2017 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 115887 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01627561 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | GlaxoSmithKline Biologicals |
| Sponsor organisation address | Rue de l'Institut 89, Rixensart, Belgium, B-1330 |
| Public contact | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com |
| Scientific contact | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|-----------------|
| Analysis stage | Interim |
| Date of interim/final analysis | 08 October 2015 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | No |

Notes:

General information about the trial

Main objective of the trial:

Safety:

To assess the safety, tolerability and occurrence of clinically relevant abnormalities in biochemistry and haematology parameters after administration of the HPV-16/18 L1 VLP AS04 vaccine according to a 2-dose schedule at 0, 6 months in 4-6 year old females, up to one month after the last dose (Month 7).

Immunogenicity:

To evaluate the immunogenicity (as determined by ELISA) of the HPV-16/18 L1 VLP AS04 vaccine administered according to a 2-dose schedule at 0, 6 months in 4-6 year old females, one month after the last dose (Month 7).

Protection of trial subjects:

All subjects were supervised after vaccination/product administration with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines.

Background therapy: -

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 15 October 2012 |
| 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 | Colombia: 26 |
| Country: Number of subjects enrolled | Mexico: 25 |
| Country: Number of subjects enrolled | Panama: 97 |
| Worldwide total number of subjects | 148 |
| 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) | 148 |

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

Out of the 149 subjects who were enrolled for the study, only 148 were registered, hence 148 started the study.

Pre-assignment

Screening details:

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

Pre-assignment period milestones

| | |
|------------------------------|--------------------|
| Number of subjects started | 149 ^[1] |
| Number of subjects completed | 148 |

Pre-assignment subject non-completion reasons

| | |
|----------------------------|-------------------|
| Reason: Number of subjects | Not registered: 1 |
|----------------------------|-------------------|

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Out of the 149 subjects who were enrolled for the study, only 148 were registered, hence 148 started the study

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Single blind |
| Roles blinded | Subject |

Blinding implementation details:

The study was single-blind until the Month 12 visit, then the study was open-label.

Arms

| | |
|------------------------------|----------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Cervarix Group |

Arm description:

Subjects aged 4-6 years receiving 2 doses of Cervarix vaccine at Day 0 and Month 6

| | |
|--|--------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Cervarix |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

2 doses administered intramuscularly in the deltoid muscle of the left arm at Day 0 and Month 6

| | |
|------------------|--------------------------|
| Arm title | Priorix + Infanrix Group |
|------------------|--------------------------|

Arm description:

Subjects aged 4-6 years receiving 1 dose of Priorix vaccine at Day 0 and 1 dose of Infanrix vaccine at Month 6

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

| | |
|--|---|
| Investigational medicinal product name | Priorix |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder and solvent for solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

1 dose administered intramuscularly in the deltoid muscle of the left/right arm at Day 0

| | |
|--|--------------------------|
| Investigational medicinal product name | Infanrix |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

1 dose administered intramuscularly in the deltoid muscle of the left/right arm at Month 6

| Number of subjects in period 1 | Cervarix Group | Priorix + Infanrix Group |
|---------------------------------------|----------------|--------------------------|
| Started | 74 | 74 |
| Completed | 74 | 71 |
| Not completed | 0 | 3 |
| Consent withdrawn by subject | - | 2 |
| Migrated/moved from study area | - | 1 |

Baseline characteristics

Reporting groups

| | |
|--|--------------------------|
| Reporting group title | Cervarix Group |
| Reporting group description: | |
| Subjects aged 4-6 years receiving 2 doses of Cervarix vaccine at Day 0 and Month 6 | |
| Reporting group title | Priorix + Infanrix Group |
| Reporting group description: | |
| Subjects aged 4-6 years receiving 1 dose of Priorix vaccine at Day 0 and 1 dose of Infanrix vaccine at Month 6 | |

| Reporting group values | Cervarix Group | Priorix + Infanrix Group | Total |
|--------------------------------|----------------|--------------------------|-------|
| Number of subjects | 74 | 74 | 148 |
| Age categorical | | | |
| Units: Subjects | | | |
| Age continuous | | | |
| Age continuous description | | | |
| Units: years | | | |
| arithmetic mean | 4.3 | 4.4 | |
| standard deviation | ± 0.48 | ± 0.52 | - |
| Gender categorical | | | |
| Gender categorical description | | | |
| Units: Subjects | | | |
| Female | 74 | 74 | 148 |
| Male | 0 | 0 | 0 |

End points

End points reporting groups

| | |
|--|--------------------------|
| Reporting group title | Cervarix Group |
| Reporting group description: | |
| Subjects aged 4-6 years receiving 2 doses of Cervarix vaccine at Day 0 and Month 6 | |
| Reporting group title | Priorix + Infanrix Group |
| Reporting group description: | |
| Subjects aged 4-6 years receiving 1 dose of Priorix vaccine at Day 0 and 1 dose of Infanrix vaccine at Month 6 | |

Primary: Number of subjects with any, Grade 3 and related solicited local symptoms.

| | |
|---|---|
| End point title | Number of subjects with any, Grade 3 and related solicited local symptoms. ^[1] |
| End point description: | |
| Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 100 millimeters (mm) of injection site. Relationship analysis was not performed. | |
| End point type | Primary |
| End point timeframe: | |
| During the 7-day period (Days 0-6) following each 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: This analysis was descriptive, hence no statistical analyses are available.

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|--|-----------------|--------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 74 | 74 | | |
| Units: Subjects | | | | |
| Any Pain Dose 1 (N=74,74) | 45 | 15 | | |
| Grade 3 Pain Dose 1 (N=74,74) | 2 | 0 | | |
| Any Redness Dose 1 (N=74,74) | 10 | 7 | | |
| Grade 3 Redness Dose 1 (N=74,74) | 1 | 0 | | |
| Any Swelling Dose 1 (N=74,74) | 6 | 6 | | |
| Grade 3 Swelling Dose 1 (N=74,74) | 1 | 0 | | |
| Any Pain Dose 2 (N=72,71) | 43 | 36 | | |
| Grade 3 Pain Dose 2 (N=72,71) | 2 | 1 | | |
| Any Redness Dose 2 (N=72,71) | 12 | 12 | | |
| Grade 3 Redness Dose 2 (N=72,71) | 0 | 4 | | |
| Any Swelling Dose 2 (N=72,71) | 16 | 15 | | |
| Grade 3 Swelling Dose 2 (N=72,71) | 3 | 7 | | |
| Any Pain Across doses (N=74,74) | 54 | 40 | | |
| Grade 3 Pain Across doses (N=74,74) | 4 | 1 | | |
| Any Redness Across doses (N=74,74) | 18 | 18 | | |
| Grade 3 Redness Across doses (N=74,74) | 1 | 4 | | |
| Any Swelling Across doses (N=74,74) | 19 | 18 | | |

| | | | | |
|--|---|---|--|--|
| Grade 3 Swelling Across doses (N=74,74) | 4 | 7 | | |
|--|---|---|--|--|

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any, Grade 3 and related solicited general symptoms.

| | |
|-----------------|---|
| End point title | Number of subjects with any, Grade 3 and related solicited general symptoms. ^[2] |
|-----------------|---|

End point description:

Assessed solicited general symptoms were arthralgia, fatigue, fever [defined as axillary temperature equal to or above 37.5 degrees Celsius (°C)], headache, myalgia, shivering and sweating. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.0 °C. Related = symptom assessed by the investigator as related to the vaccination.

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

End point timeframe:

During the 7-day period (Days 0-6) following each vaccination

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 analysis was descriptive, hence no statistical analyses are available.

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|--|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 74 | 74 | | |
| Units: Subjects | | | | |
| Any Arthralgia Dose 1 (N=74,74) | 5 | 8 | | |
| Grade 3 Arthralgia Dose 1 (N=74,74) | 0 | 0 | | |
| Related Arthralgia Dose 1 (N=74,74) | 4 | 8 | | |
| Any Drowsiness Dose 1 (N=74,74) | 14 | 7 | | |
| Grade 3 Drowsiness Dose 1 (N=74,74) | 3 | 0 | | |
| Related Drowsiness Dose 1 (N=74,74) | 12 | 7 | | |
| Any Fatigue Dose 1 (N=74,74) | 8 | 7 | | |
| Grade 3 Fatigue Dose 1 (N=74,74) | 0 | 0 | | |
| Related Fatigue Dose 1 (N=74,74) | 7 | 7 | | |
| Any Fever Dose 1 (N=74,74) | 6 | 8 | | |
| Grade 3 Fever Dose 1 (N=74,74) | 1 | 0 | | |
| Related Fever Dose 1 (N=74,74) | 3 | 5 | | |
| Any Gastrointestinal Dose 1 (N=74,74) | 7 | 12 | | |
| Grade 3 Gastrointestinal Dose 1 (N=74,74) | 0 | 0 | | |
| Related Gastrointestinal Dose 1 (N=74,74) | 5 | 10 | | |
| Any Headache Dose 1 (N=74,74) | 11 | 19 | | |
| Grade 3 Headache Dose 1 (N=74,74) | 0 | 1 | | |
| Related Headache Dose 1 (N=74,74) | 9 | 16 | | |
| Any Irritability Dose 1 (N=74,74) | 13 | 7 | | |

| | | | | |
|---|----|----|--|--|
| Grade 3 Irritability Dose 1 (N=74,74) | 1 | 0 | | |
| Related Irritability Dose 1 (N=74,74) | 12 | 7 | | |
| Any Loss of appetite Dose 1 (N=74,74) | 15 | 7 | | |
| Grade 3 Loss of appetite Dose 1 (N=74,74) | 0 | 0 | | |
| Related Loss of appetite Dose 1 (N=74,74) | 13 | 7 | | |
| Any Myalgia Dose 1 (N=74,74) | 13 | 9 | | |
| Grade 3 Myalgia Dose 1 (N=74,74) | 0 | 0 | | |
| Related Myalgia Dose 1 (N=74,74) | 13 | 9 | | |
| Any Rash Dose 1 (N=74,74) | 3 | 1 | | |
| Grade 3 Rash Dose 1 (N=74,74) | 0 | 0 | | |
| Related Rash Dose 1 (N=74,74) | 2 | 1 | | |
| Any Urticaria Dose 1 (N=74,74) | 5 | 3 | | |
| Grade 3 Urticaria Dose 1 (N=74,74) | 0 | 0 | | |
| Related Urticaria Dose 1 (N=74,74) | 4 | 2 | | |
| Any Arthralgia Dose 2 (N=72,71) | 10 | 8 | | |
| Grade 3 Arthralgia Dose 2 (N=72,71) | 0 | 0 | | |
| Related Arthralgia Dose 2 (N=72,71) | 9 | 8 | | |
| Any Drowsiness Dose 2 (N=72,71) | 9 | 9 | | |
| Grade 3 Drowsiness Dose 2 (N=72,71) | 0 | 0 | | |
| Related Drowsiness Dose 2 (N=72,71) | 9 | 9 | | |
| Any Fatigue Dose 2 (N=72,71) | 9 | 7 | | |
| Grade 3 Fatigue Dose 2 (N=72,71) | 0 | 0 | | |
| Related Fatigue Dose 2 (N=72,71) | 8 | 7 | | |
| Any Fever Dose 2 (N=72,71) | 7 | 12 | | |
| Grade 3 Fever Dose 2 (N=72,71) | 0 | 0 | | |
| Related Fever Dose 2 (N=72,71) | 6 | 9 | | |
| Any Gastrointestinal Dose 2 (N=72,71) | 4 | 9 | | |
| Grade 3 Gastrointestinal Dose 2 (N=72,71) | 0 | 0 | | |
| Related Gastrointestinal Dose 2 (N=72,71) | 2 | 8 | | |
| Any Headache Dose 2 (N=72,71) | 12 | 13 | | |
| Grade 3 Headache Dose 2 (N=72,71) | 0 | 0 | | |
| Related Headache Dose 2 (N=72,71) | 12 | 12 | | |
| Any Irritability Dose 2 (N=72,71) | 18 | 17 | | |
| Grade 3 Irritability Dose 2 (N=72,71) | 0 | 0 | | |
| Related Irritability Dose 2 (N=72,71) | 18 | 17 | | |
| Any Loss of appetite Dose 2 (N=72,71) | 9 | 8 | | |
| Grade 3 Loss of appetite Dose 2 (N=72,71) | 1 | 1 | | |
| Related Loss of appetite Dose 2 (N=72,71) | 8 | 8 | | |
| Any Myalgia Dose 2 (N=72,71) | 13 | 11 | | |
| Grade 3 Myalgia Dose 2 (N=72,71) | 0 | 0 | | |
| Related Myalgia Dose 2 (N=72,71) | 12 | 11 | | |
| Any Rash Dose 2 (N=72,71) | 3 | 4 | | |
| Grade 3 Rash Dose 2 (N=72,71) | 0 | 0 | | |
| Related Rash Dose 2 (N=72,71) | 3 | 3 | | |
| Any Urticaria Dose 2 (N=72,71) | 5 | 4 | | |
| Grade 3 Urticaria Dose 2 (N=72,71) | 0 | 0 | | |
| Related Urticaria Dose 2 (N=72,71) | 4 | 3 | | |
| Any Arthralgia Across doses (N=74,74) | 13 | 11 | | |

| | | | | |
|---|----|----|--|--|
| Grade 3 Arthralgia Across doses (N=74,74) | 0 | 0 | | |
| Related Arthralgia Across doses (N=74,74) | 12 | 11 | | |
| Any Drowsiness Across doses (N=74,74) | 16 | 15 | | |
| Grade 3 Drowsiness Across doses (N=74,74) | 3 | 0 | | |
| Related Drowsiness Across doses (N=74,74) | 15 | 15 | | |
| Any Fatigue Across doses (N=74,74) | 15 | 10 | | |
| Grade 3 Fatigue Across doses (N=74,74) | 0 | 0 | | |
| Related Fatigue Across doses (N=74,74) | 13 | 10 | | |
| Any Fever Across doses (N=74,74) | 12 | 17 | | |
| Grade 3 Fever Across doses (N=74,74) | 1 | 0 | | |
| Related Fever Across doses (N=74,74) | 8 | 13 | | |
| Any Gastrointestinal Across doses (N=74,74) | 11 | 16 | | |
| Grade 3 Gastrointestinal Across doses (N=74,74) | 0 | 0 | | |
| Related Gastrointestinal Across doses (N=74,74) | 7 | 15 | | |
| Any Headache Across doses (N=74,74) | 18 | 25 | | |
| Grade 3 Headache Across doses (N=74,74) | 0 | 1 | | |
| Related Headache Across doses (N=74,74) | 16 | 22 | | |
| Any Irritability Across doses (N=74,74) | 22 | 19 | | |
| Grade 3 Irritability Across doses (N=74,74) | 1 | 0 | | |
| Related Irritability Across doses (N=74,74) | 22 | 19 | | |
| Any Loss of appetite Across doses (N=74,74) | 21 | 13 | | |
| Grade 3 Loss of appetite Across doses (N=74,74) | 1 | 1 | | |
| Related Loss of appetite Across doses (N=74,74) | 18 | 13 | | |
| Any Myalgia Across doses (N=74,74) | 21 | 14 | | |
| Grade 3 Myalgia Across doses (N=74,74) | 0 | 0 | | |
| Related Myalgia Across doses (N=74,74) | 21 | 14 | | |
| Any Rash Across doses (N=74,74) | 6 | 5 | | |
| Grade 3 Rash Across doses (N=74,74) | 0 | 0 | | |
| Related Rash Across doses (N=74,74) | 5 | 4 | | |
| Any Urticaria Across doses (N=74,74) | 10 | 7 | | |
| Grade 3 Urticaria Across doses (N=74,74) | 0 | 0 | | |
| Related Urticaria Across doses (N=74,74) | 8 | 5 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with unsolicited any, Grade 3 and related adverse events (AEs).

| | |
|-----------------|---|
| End point title | Number of subjects with unsolicited any, Grade 3 and related adverse events (AEs). ^[3] |
|-----------------|---|

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities. Related = AE assessed by the investigator as related to the vaccination.

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

End point timeframe:

During the 43-day period (Days 0-42) post vaccination Dose 1

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: This analysis was descriptive, hence no statistical analyses are available.

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|-----------------------------|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 74 | 74 | | |
| Units: Subjects | | | | |
| Any AEs | 40 | 40 | | |
| Grade 3 AEs | 3 | 2 | | |
| Related AEs | 1 | 5 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with unsolicited any, Grade 3 and related adverse events (AEs).

| | |
|-----------------|---|
| End point title | Number of subjects with unsolicited any, Grade 3 and related adverse events (AEs). ^[4] |
|-----------------|---|

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities. Related = AE assessed by the investigator as related to the vaccination.

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

End point timeframe:

During the 30-day period (Days 0-29) post vaccination Dose 2 at Month 6

Notes:

[4] - 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 analysis was descriptive, hence no statistical analyses are available.

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|-----------------------------|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 74 | 71 | | |
| Units: Subjects | | | | |
| Any AEs | 18 | 13 | | |
| Grade 3 AEs | 0 | 0 | | |
| Related AEs | 1 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with clinically relevant abnormalities in biochemical and haematological parameters.

| | |
|-----------------|--|
| End point title | Number of subjects with clinically relevant abnormalities in biochemical and haematological parameters. ^[5] |
|-----------------|--|

End point description:

The parameters assessed were both biochemical (alanine aminotransferase = ALAT, creatinine = CREA, urea nitrogen = BUN) and haematological (basophils = BAS, eosinophils = EOS, red blood cells = RBC, hematocrit = HCT, hemoglobin, leukocytes [white blood cells] = WBC, lymphocytes, monocytes, neutrophils and platelets). Results were split into 2 outcomes due to the table size. Note that "99999" is a placeholder value since the number of subjects the respective categories was 0, hence the statistical analysis could not be performed.

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

End point timeframe:

42 days post dose 1 (PRE) and at 30 days post dose 2 (POST)

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: This analysis was descriptive, hence no statistical analyses are available.

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|------------------------------------|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 72 | 69 | | |
| Units: Subjects | | | | |
| ALAT, PRE Unknown Unknown [N=2;2] | 0 | 0 | | |
| ALAT, PRE Unknown Below [N=2;2] | 0 | 0 | | |
| ALAT, PRE Unknown Within [N=2;2] | 2 | 2 | | |
| ALAT, PRE Unknown Above [N=2;2] | 0 | 0 | | |
| ALAT, PRE Below Unknown [N=2;1] | 0 | 0 | | |
| ALAT, PRE Below Below [N=2;1] | 1 | 0 | | |
| ALAT, PRE Below Within [N=2;1] | 1 | 1 | | |
| ALAT, PRE Below Above [N=2;1] | 0 | 0 | | |
| ALAT, PRE Within Unknown [N=67;64] | 0 | 0 | | |
| ALAT, PRE Within Below [N=67;64] | 0 | 0 | | |
| ALAT, PRE Within Within [N=67;64] | 64 | 62 | | |
| ALAT, PRE Within Above [N=67;64] | 3 | 2 | | |
| ALAT, PRE Above Unknown [N=3;5] | 0 | 0 | | |
| ALAT, PRE Above Below [N=3;5] | 0 | 0 | | |
| ALAT, PRE Above Within [N=3;5] | 1 | 3 | | |

| | | | | |
|-------------------------------------|-------|-------|--|--|
| ALAT, PRE Above Above [N=3;5] | 2 | 2 | | |
| ALAT, POST Unknown Unknown [N=2;2] | 0 | 0 | | |
| ALAT, POST Unknown Below [N=2;2] | 0 | 0 | | |
| ALAT, POST Unknown Within [N=2;2] | 2 | 2 | | |
| ALAT, POST Unknown Above [N=2;2] | 0 | 0 | | |
| ALAT, POST Below Unknown [N=2;1] | 0 | 0 | | |
| ALAT, POST Below Below [N=2;1] | 1 | 0 | | |
| ALAT, POST Below Within [N=2;1] | 1 | 1 | | |
| ALAT, POST Below Above [N=2;1] | 0 | 0 | | |
| ALAT, POST Within Unknown [N=66;64] | 0 | 0 | | |
| ALAT, POST Within Below [N=66;64] | 2 | 2 | | |
| ALAT, POST Within Within [N=66;64] | 64 | 61 | | |
| ALAT, POST Within Above [N=66;64] | 0 | 1 | | |
| ALAT, POST Above Unknown [N=3;5] | 0 | 0 | | |
| ALAT, POST Above Below [N=3;5] | 0 | 0 | | |
| ALAT, POST Above Within [N=3;5] | 2 | 5 | | |
| ALAT, POST Above Above [N=3;5] | 1 | 0 | | |
| BAS, PRE Unknown Unknown [N=2;0] | 0 | 99999 | | |
| BAS, PRE Unknown Below [N=2;0] | 0 | 99999 | | |
| BAS, PRE Unknown Within [N=2;0] | 2 | 99999 | | |
| BAS, PRE Unknown Above [N=2;0] | 0 | 99999 | | |
| BAS, PRE Below Unknown [N=0;0] | 99999 | 99999 | | |
| BAS, PRE Below Below [N=0;0] | 99999 | 99999 | | |
| BAS, PRE Below Within [N=0;0] | 99999 | 99999 | | |
| BAS, PRE Below Above [N=0;0] | 99999 | 99999 | | |
| BAS, PRE Within Unknown [N=70;69] | 0 | 0 | | |
| BAS, PRE Within Below [N=70;69] | 0 | 0 | | |
| BAS, PRE Within Within [N=70;69] | 70 | 69 | | |
| BAS, PRE Within Above [N=70;69] | 0 | 0 | | |
| BAS, PRE Above Unknown [N=0;4] | 99999 | 0 | | |
| BAS, PRE Above Below [N=0;4] | 99999 | 0 | | |
| BAS, PRE Above Within [N=0;4] | 99999 | 4 | | |
| BAS, PRE Above Above [N=0;4] | 99999 | 0 | | |
| BAS, POST Unknown Unknown [N=2;0] | 0 | 99999 | | |
| BAS, POST Unknown Below [N=2;0] | 0 | 99999 | | |
| BAS, POST Unknown Within [N=2;0] | 2 | 99999 | | |
| BAS, POST Unknown Above [N=2;0] | 0 | 99999 | | |
| BAS, POST Below Unknown [N=0;0] | 99999 | 99999 | | |
| BAS, POST Below Below [N=0;0] | 99999 | 99999 | | |
| BAS, POST Below Within [N=0;0] | 99999 | 99999 | | |
| BAS, POST Below Above [N=0;0] | 99999 | 99999 | | |
| BAS, POST Within Unknown [N=72;68] | 0 | 0 | | |
| BAS, POST Within Below [N=72;68] | 0 | 0 | | |
| BAS, POST Within Within [N=72;68] | 71 | 67 | | |
| BAS, POST Within Above [N=72;68] | 1 | 1 | | |
| BAS, POST Above Unknown [N=0;4] | 99999 | 0 | | |
| BAS, POST Above Below [N=0;4] | 99999 | 0 | | |
| BAS, POST Above Within [N=0;4] | 99999 | 2 | | |
| BAS, POST Above Above [N=0;4] | 99999 | 2 | | |
| CREA, PRE Unknown Unknown [N=2;1] | 0 | 0 | | |
| CREA, PRE Unknown Below [N=2;1] | 0 | 0 | | |
| CREA, PRE Unknown Within [N=2;1] | 2 | 1 | | |

| | | | | |
|---------------------------------------|-------|-------|--|--|
| CREA, PRE Unknown Above [N=2;1] | 0 | 0 | | |
| CREA, PRE Below Unknown [N=27;22] | 0 | 0 | | |
| CREA, PRE Below Below [N=27;22] | 20 | 15 | | |
| CREA, PRE Below Within [N=27;22] | 7 | 7 | | |
| CREA, PRE Below Above [N=27;22] | 0 | 0 | | |
| CREA, PRE Within Unknown [N=45;49] | 0 | 1 | | |
| CREA, PRE Within Below [N=45;49] | 7 | 12 | | |
| CREA, PRE Within Within [N=45;49] | 38 | 36 | | |
| CREA, PRE Within Above [N=45;49] | 0 | 0 | | |
| CREA, PRE Above Unknown [N=0;1] | 99999 | 0 | | |
| CREA, PRE Above Below [N=0;1] | 99999 | 0 | | |
| CREA, PRE Above Within [N=0;1] | 99999 | 1 | | |
| CREA, PRE Above Above [N=0;1] | 99999 | 0 | | |
| CREA, POST Unknown Unknown [N=2;1] | 0 | 0 | | |
| CREA, POST Unknown Below [N=2;1] | 1 | 0 | | |
| CREA, POST Unknown Within [N=2;1] | 1 | 1 | | |
| CREA, POST Unknown Above [N=2;1] | 0 | 0 | | |
| CREA, POST Below Unknown [N=26;22] | 0 | 0 | | |
| CREA, POST Below Below [N=26;22] | 20 | 18 | | |
| CREA, POST Below Within [N=26;22] | 6 | 4 | | |
| CREA, POST Below Above [N=26;22] | 0 | 0 | | |
| CREA, POST Within Unknown [N=45;48] | 0 | 1 | | |
| CREA, POST Within Below [N=45;48] | 11 | 11 | | |
| CREA, POST Within Within [N=45;48] | 34 | 36 | | |
| CREA, POST Within Above [N=45;48] | 0 | 0 | | |
| CREA, POST Above Unknown [N=0;1] | 99999 | 0 | | |
| CREA, POST Above Below [N=0;1] | 99999 | 1 | | |
| CREA, POST Above Within [N=0;1] | 99999 | 0 | | |
| CREA, POST Above Above [N=0;1] | 99999 | 0 | | |
| EOS, PRE Unknown Unknown [N=2;0] | 0 | 99999 | | |
| EOS, PRE Unknown Below [N=2;0] | 0 | 99999 | | |
| EOS, PRE Unknown Within [N=2;0] | 2 | 99999 | | |
| EOS, PRE Unknown Above [N=2;0] | 0 | 99999 | | |
| EOS, PRE Below Unknown [N=1;0] | 0 | 99999 | | |
| EOS, PRE Below Below [N=1;0] | 0 | 99999 | | |
| EOS, PRE Below Within [N=1;0] | 1 | 99999 | | |
| EOS, PRE Below Above [N=1;0] | 0 | 99999 | | |
| EOS, PRE Within Unknown [N=49;50] | 0 | 0 | | |
| EOS, PRE Within Below [N=49;50] | 1 | 1 | | |
| EOS, PRE Within Within [N=49;50] | 41 | 38 | | |
| EOS, PRE Within Above [N=49;50] | 7 | 11 | | |
| EOS, PRE Above Unknown [N=20;23] | 0 | 0 | | |
| EOS, PRE Above Below [N=20;23] | 0 | 1 | | |
| EOS, PRE Above Within [N=20;23] | 3 | 10 | | |
| EOS, PRE Above Above [N=20;23] | 17 | 12 | | |
| EOS, POST Unknown Unknown [N=2;0] | 0 | 99999 | | |
| EOS, POST Unknown Below [N=2;0] | 0 | 99999 | | |
| EOS, POST Unknown Within [N=2;0] | 2 | 99999 | | |
| EOS, POST Unknown Above [N=2;0] | 0 | 99999 | | |
| EOS, POST Below Unknown [N=1;0] | 0 | 99999 | | |
| EOS, POST Below Below [N=1;0] | 0 | 99999 | | |

| | | | | |
|------------------------------------|-------|-------|--|--|
| EOS, POST Below Within [N=1;0] | 1 | 99999 | | |
| EOS, POST Below Above [N=1;0] | 0 | 99999 | | |
| EOS, POST Within Unknown [N=51;49] | 0 | 0 | | |
| EOS, POST Within Below [N=51;49] | 0 | 1 | | |
| EOS, POST Within Within [N=51;49] | 42 | 35 | | |
| EOS, POST Within Above [N=51;49] | 9 | 13 | | |
| EOS, POST Above Unknown [N=20;23] | 0 | 0 | | |
| EOS, POST Above Below [N=20;23] | 0 | 0 | | |
| EOS, POST Above Within [N=20;23] | 2 | 10 | | |
| EOS, POST Above Above [N=20;23] | 18 | 13 | | |
| RBC, PRE Unknown Unknown [N=2;0] | 0 | 99999 | | |
| RBC, PRE Unknown Below [N=2;0] | 0 | 99999 | | |
| RBC, PRE Unknown Within [N=2;0] | 2 | 99999 | | |
| RBC, PRE Unknown Above [N=2;0] | 0 | 99999 | | |
| RBC, PRE Below Unknown [N=4;4] | 0 | 0 | | |
| RBC, PRE Below Below [N=4;4] | 0 | 0 | | |
| RBC, PRE Below Within [N=4;4] | 4 | 4 | | |
| RBC, PRE Below Above [N=4;4] | 0 | 0 | | |
| RBC, PRE Within Unknown [N=66;66] | 0 | 0 | | |
| RBC, PRE Within Below [N=66;66] | 3 | 2 | | |
| RBC, PRE Within Within [N=66;66] | 61 | 63 | | |
| RBC, PRE Within Above [N=66;66] | 2 | 1 | | |
| RBC, PRE Above Unknown [N=0;3] | 99999 | 0 | | |
| RBC, PRE Above Below [N=0;3] | 99999 | 0 | | |
| RBC, PRE Above Within [N=0;3] | 99999 | 2 | | |
| RBC, PRE Above Above [N=0;3] | 99999 | 1 | | |
| RBC, POST Unknown Unknown [N=2;0] | 0 | 99999 | | |
| RBC, POST Unknown Below [N=2;0] | 0 | 99999 | | |
| RBC, POST Unknown Within [N=2;0] | 2 | 99999 | | |
| RBC, POST Unknown Above [N=2;0] | 0 | 99999 | | |
| RBC, POST Below Unknown [N=4;4] | 0 | 0 | | |
| RBC, POST Below Below [N=4;4] | 0 | 2 | | |
| RBC, POST Below Within [N=4;4] | 4 | 2 | | |
| RBC, POST Below Above [N=4;4] | 0 | 0 | | |
| RBC, POST Within Unknown [N=68;65] | 0 | 0 | | |
| RBC, POST Within Below [N=68;65] | 2 | 2 | | |
| RBC, POST Within Within [N=68;65] | 65 | 63 | | |
| RBC, POST Within Above [N=68;65] | 1 | 0 | | |
| RBC, POST Above Unknown [N=0;3] | 99999 | 0 | | |
| RBC, POST Above Below [N=0;3] | 99999 | 0 | | |
| RBC, POST Above Within [N=0;3] | 99999 | 2 | | |
| RBC, POST Above Above [N=0;3] | 99999 | 1 | | |
| HCT, PRE Unknown Unknown [N=2;0] | 0 | 99999 | | |
| HCT, PRE Unknown Below [N=2;0] | 0 | 99999 | | |
| HCT, PRE Unknown Within [N=2;0] | 2 | 99999 | | |
| HCT, PRE Unknown Above [N=2;0] | 0 | 99999 | | |
| HCT, PRE Below Unknown [N=19;21] | 0 | 0 | | |
| HCT, PRE Below Below [N=19;21] | 8 | 12 | | |
| HCT, PRE Below Within [N=19;21] | 11 | 8 | | |
| HCT, PRE Below Above [N=19;21] | 0 | 1 | | |
| HCT, PRE Within Unknown [N=48;48] | 0 | 0 | | |
| HCT, PRE Within Below [N=48;48] | 5 | 1 | | |

| | | | | |
|--|----|-------|--|--|
| HCT, PRE Within Within [N=48;48] | 41 | 42 | | |
| HCT, PRE Within Above [N=48;48] | 2 | 5 | | |
| HCT, PRE Above Unknown [N=3;4] | 0 | 0 | | |
| HCT, PRE Above Below [N=3;4] | 0 | 0 | | |
| HCT, PRE Above Within [N=3;4] | 2 | 4 | | |
| HCT, PRE Above Above [N=3;4] | 1 | 0 | | |
| HCT, POST Unknown Unknown [N=2;0] | 0 | 99999 | | |
| HCT, POST Unknown Below [N=2;0] | 0 | 99999 | | |
| HCT, POST Unknown Within [N=2;0] | 1 | 99999 | | |
| HCT, POST Unknown Above [N=2;0] | 1 | 99999 | | |
| HCT, POST Below Unknown [N=20;21] | 0 | 0 | | |
| HCT, POST Below Below [N=20;21] | 5 | 10 | | |
| HCT, POST Below Within [N=20;21] | 15 | 11 | | |
| HCT, POST Below Above [N=20;21] | 0 | 0 | | |
| HCT, POST Within Unknown [N=49;47] | 0 | 0 | | |
| HCT, POST Within Below [N=49;47] | 3 | 3 | | |
| HCT, POST Within Within [N=49;47] | 45 | 44 | | |
| HCT, POST Within Above [N=49;47] | 1 | 0 | | |
| HCT, POST Above Unknown [N=3;4] | 0 | 0 | | |
| HCT, POST Above Below [N=3;4] | 0 | 0 | | |
| HCT, POST Above Within [N=3;4] | 3 | 4 | | |
| HCT, POST Above Above [N=3;4] | 0 | 0 | | |
| Hemoglobin, PRE Unknown Unknown [N=2;0] | 0 | 99999 | | |
| Hemoglobin, PRE Unknown Below [N=2;0] | 0 | 99999 | | |
| Hemoglobin, PRE Unknown Within [N=2;0] | 1 | 99999 | | |
| Hemoglobin, PRE Unknown Above [N=2;0] | 1 | 99999 | | |
| Hemoglobin, PRE Below Unknown [N=15;11] | 0 | 0 | | |
| Hemoglobin, PRE Below Below [N=15;11] | 7 | 2 | | |
| Hemoglobin, PRE Below Within [N=15;11] | 8 | 9 | | |
| Hemoglobin, PRE Below Above [N=15;11] | 0 | 0 | | |
| Hemoglobin, PRE Within Unknown [N=50;56] | 0 | 0 | | |
| Hemoglobin, PRE Within Below [N=50;56] | 3 | 6 | | |
| Hemoglobin, PRE Within Within [N=50;56] | 43 | 46 | | |
| Hemoglobin, PRE Within Above [N=50;56] | 4 | 4 | | |
| Hemoglobin, PRE Above Unknown [N=5;6] | 0 | 0 | | |
| Hemoglobin, PRE Above Below [N=5;6] | 0 | 0 | | |
| Hemoglobin, PRE Above Within [N=5;6] | 3 | 5 | | |
| Hemoglobin, PRE Above Above [N=5;6] | 2 | 1 | | |
| Hemoglobin, POST Unknown Unknown [N=2;0] | 0 | 99999 | | |
| Hemoglobin, POST Unknown Below [N=2;0] | 0 | 99999 | | |
| Hemoglobin, POST Unknown Within [N=2;0] | 1 | 99999 | | |

| | | | | |
|---|----|-------|--|--|
| Hemoglobin, POST Unknown Above [N=2;0] | 1 | 99999 | | |
| Hemoglobin, POST Below Unknown [N=16;11] | 0 | 0 | | |
| Hemoglobin, POST Below Below [N=16;11] | 1 | 2 | | |
| Hemoglobin, POST Below Within [N=16;11] | 15 | 9 | | |
| Hemoglobin, POST Below Above [N=16;11] | 0 | 0 | | |
| Hemoglobin, POST Within Unknown [N=51;55] | 0 | 0 | | |
| Hemoglobin, POST Within Below [N=51;55] | 1 | 4 | | |
| Hemoglobin, POST Within Within [N=51;55] | 44 | 50 | | |
| Hemoglobin, POST Within Above [N=51;55] | 6 | 1 | | |
| Hemoglobin, POST Above Unknown [N=5;6] | 0 | 0 | | |
| Hemoglobin, POST Above Below [N=5;6] | 0 | 0 | | |
| Hemoglobin, POST Above Within [N=5;6] | 3 | 5 | | |
| Hemoglobin, POST Above Above [N=5;6] | 2 | 1 | | |
| WBC, PRE Unknown Unknown [N=2;0] | 0 | 99999 | | |
| WBC, PRE Unknown Below [N=2;0] | 0 | 99999 | | |
| WBC, PRE Unknown Within [N=2;0] | 1 | 99999 | | |
| WBC, PRE Unknown Above [N=2;0] | 1 | 99999 | | |
| WBC, PRE Below Unknown [N=5;7] | 0 | 0 | | |
| WBC, PRE Below Below [N=5;7] | 1 | 5 | | |
| WBC, PRE Below Within [N=5;7] | 3 | 1 | | |
| WBC, PRE Below Above [N=5;7] | 1 | 1 | | |
| WBC, PRE Within Unknown [N=62;61] | 0 | 0 | | |
| WBC, PRE Within Below [N=62;61] | 3 | 1 | | |
| WBC, PRE Within Within [N=62;61] | 56 | 57 | | |
| WBC, PRE Within Above [N=62;61] | 3 | 3 | | |
| WBC, PRE Above Unknown [N=3;5] | 0 | 0 | | |
| WBC, PRE Above Below [N=3;5] | 0 | 0 | | |
| WBC, PRE Above Within [N=3;5] | 1 | 3 | | |
| WBC, PRE Above Above [N=3;5] | 2 | 2 | | |
| WBC, POST Unknown Unknown [N=2;0] | 0 | 99999 | | |
| WBC, POST Unknown Below [N=2;0] | 0 | 99999 | | |
| WBC, POST Unknown Within [N=2;0] | 2 | 99999 | | |
| WBC, POST Unknown Above [N=2;0] | 0 | 99999 | | |
| WBC, POST Below Unknown [N=5;7] | 0 | 0 | | |
| WBC, POST Below Below [N=5;7] | 3 | 4 | | |
| WBC, POST Below Within [N=5;7] | 2 | 3 | | |
| WBC, POST Below Above [N=5;7] | 0 | 0 | | |
| WBC, POST Within Unknown [N=63;60] | 0 | 0 | | |
| WBC, POST Within Below [N=63;60] | 1 | 7 | | |
| WBC, POST Within Within [N=63;60] | 60 | 50 | | |
| WBC, POST Within Above [N=63;60] | 2 | 3 | | |
| WBC, POST Above Unknown [N=4;5] | 0 | 0 | | |
| WBC, POST Above Below [N=4;5] | 0 | 0 | | |

| | | | | |
|--|----|-------|--|--|
| WBC, POST Above Within [N=4;5] | 2 | 4 | | |
| WBC, POST Above Above [N=4;5] | 2 | 1 | | |
| Lymphocytes, PRE Unknown Unknown [N=2;0] | 0 | 99999 | | |
| Lymphocytes, PRE Unknown Below [N=2;0] | 0 | 99999 | | |
| Lymphocytes, PRE Unknown Within [N=2;0] | 1 | 99999 | | |
| Lymphocytes, PRE Unknown Above [N=2;0] | 1 | 99999 | | |
| Lymphocytes, PRE Below Unknown [N=7;10] | 0 | 0 | | |
| Lymphocytes, PRE Below Below [N=7;10] | 4 | 6 | | |
| Lymphocytes, PRE Below Within [N=7;10] | 2 | 2 | | |
| Lymphocytes, PRE Below Above [N=7;10] | 1 | 2 | | |
| Lymphocytes, PRE Within Unknown [N=48;42] | 0 | 0 | | |
| Lymphocytes, PRE Within Below [N=48;42] | 7 | 2 | | |
| Lymphocytes, PRE Within Within [N=48;42] | 38 | 34 | | |
| Lymphocytes, PRE Within Above [N=48;42] | 3 | 6 | | |
| Lymphocytes, PRE Above Unknown [N=15;21] | 0 | 0 | | |
| Lymphocytes, PRE Above Below [N=15;21] | 0 | 2 | | |
| Lymphocytes, PRE Above Within [N=15;21] | 6 | 5 | | |
| Lymphocytes, PRE Above Above [N=15;21] | 9 | 14 | | |
| Lymphocytes, POST Unknown Unknown [N=2;0] | 0 | 99999 | | |
| Lymphocytes, POST Unknown Below [N=2;0] | 0 | 99999 | | |
| Lymphocytes, POST Unknown Within [N=2;0] | 2 | 99999 | | |
| Lymphocytes, POST Unknown Above [N=2;0] | 0 | 99999 | | |
| Lymphocytes, POST Below Unknown [N=7;10] | 0 | 0 | | |
| Lymphocytes, POST Below Below [N=7;10] | 6 | 6 | | |
| Lymphocytes, POST Below Within [N=7;10] | 1 | 4 | | |
| Lymphocytes, POST Below Above [N=7;10] | 0 | 0 | | |
| Lymphocytes, POST Within Unknown [N=49;42] | 0 | 0 | | |
| Lymphocytes, POST Within Below [N=49;42] | 6 | 5 | | |
| Lymphocytes, POST Within Within [N=49;42] | 38 | 37 | | |
| Lymphocytes, POST Within Above [N=49;42] | 5 | 0 | | |
| Lymphocytes, POST Above Unknown [N=16;20] | 0 | 0 | | |
| Lymphocytes, POST Above Below [N=16;20] | 0 | 1 | | |

| | | | | |
|--|----|-------|--|--|
| Lymphocytes, POST Above Within [N=16;20] | 16 | 15 | | |
| Lymphocytes, POST Above Above [N=16;20] | 0 | 4 | | |
| Monocytes, PRE Unknown Unknown [N=2;0] | 0 | 99999 | | |
| Monocytes, PRE Unknown Below [N=2;0] | 1 | 99999 | | |
| Monocytes, PRE Unknown Within [N=2;0] | 1 | 99999 | | |
| Monocytes, PRE Unknown Above [N=2;0] | 0 | 99999 | | |
| Monocytes, PRE Below Unknown [N=7;9] | 0 | 0 | | |
| Monocytes, PRE Below Below [N=7;9] | 4 | 5 | | |
| Monocytes, PRE Below Within [N=7;9] | 3 | 4 | | |
| Monocytes, PRE Below Above [N=7;9] | 0 | 0 | | |
| Monocytes, PRE Within Unknown [N=51;55] | 0 | 0 | | |
| Monocytes, PRE Within Below [N=51;55] | 3 | 2 | | |
| Monocytes, PRE Within Within [N=51;55] | 42 | 48 | | |
| Monocytes, PRE Within Above [N=51;55] | 6 | 5 | | |
| Monocytes, PRE Above Unknown [N=12;9] | 0 | 0 | | |
| Monocytes, PRE Above Below [N=12;9] | 0 | 0 | | |
| Monocytes, PRE Above Within [N=12;9] | 6 | 3 | | |
| Monocytes, PRE Above Above [N=12;9] | 6 | 6 | | |
| Monocytes, POST Unknown Unknown [N=2;0] | 0 | 99999 | | |
| Monocytes, POST Unknown Below [N=2;0] | 1 | 99999 | | |
| Monocytes, POST Unknown Within [N=2;0] | 1 | 99999 | | |
| Monocytes, POST Unknown Above [N=2;0] | 0 | 99999 | | |
| Monocytes, POST Below Unknown [N=7;9] | 0 | 0 | | |
| Monocytes, POST Below Below [N=7;9] | 2 | 4 | | |
| Monocytes, POST Below Within [N=7;9] | 5 | 4 | | |
| Monocytes, POST Below Above [N=7;9] | 0 | 1 | | |
| Monocytes, POST Within Unknown [N=53;54] | 0 | 0 | | |
| Monocytes, POST Within Below [N=53;54] | 4 | 3 | | |
| Monocytes, POST Within Within [N=53;54] | 49 | 51 | | |
| Monocytes, POST Within Above [N=53;54] | 0 | 0 | | |
| Monocytes, POST Above Unknown [N=12;9] | 0 | 0 | | |
| Monocytes, POST Above Below [N=12;9] | 0 | 0 | | |
| Monocytes, POST Above Within [N=12;9] | 12 | 7 | | |
| Monocytes, POST Above Above [N=12;9] | 0 | 2 | | |

| | | | | |
|--|----|-------|--|--|
| Neutrophils, PRE Unknown Unknown [N=2;0] | 0 | 99999 | | |
| Neutrophils, PRE Unknown Below [N=2;0] | 1 | 99999 | | |
| Neutrophils, PRE Unknown Within [N=2;0] | 1 | 99999 | | |
| Neutrophils, PRE Unknown Above [N=2;0] | 0 | 99999 | | |
| Neutrophils, PRE Below Unknown [N=14;21] | 0 | 0 | | |
| Neutrophils, PRE Below Below [N=14;21] | 8 | 14 | | |
| Neutrophils, PRE Below Within [N=14;21] | 6 | 6 | | |
| Neutrophils, PRE Below Above [N=14;21] | 0 | 1 | | |
| Neutrophils, PRE Within Unknown [N=52;46] | 0 | 0 | | |
| Neutrophils, PRE Within Below [N=52;46] | 4 | 6 | | |
| Neutrophils, PRE Within Within [N=52;46] | 41 | 39 | | |
| Neutrophils, PRE Within Above [N=52;46] | 7 | 1 | | |
| Neutrophils, PRE Above Unknown [N=4;6] | 0 | 0 | | |
| Neutrophils, PRE Above Below [N=4;6] | 0 | 0 | | |
| Neutrophils, PRE Above Within [N=4;6] | 3 | 3 | | |
| Neutrophils, PRE Above Above [N=4;6] | 1 | 3 | | |
| Neutrophils, POST Unknown Unknown [N=2;0] | 0 | 99999 | | |
| Neutrophils, POST Unknown Below [N=2;0] | 0 | 99999 | | |
| Neutrophils, POST Unknown Within [N=2;0] | 2 | 99999 | | |
| Neutrophils, POST Unknown Above [N=2;0] | 0 | 99999 | | |
| Neutrophils, POST Below Unknown [N=15;21] | 0 | 0 | | |
| Neutrophils, POST Below Below [N=15;21] | 1 | 4 | | |
| Neutrophils, POST Below Within [N=15;21] | 13 | 16 | | |
| Neutrophils, POST Below Above [N=15;21] | 1 | 1 | | |
| Neutrophils, POST Within Unknown [N=53;45] | 0 | 0 | | |
| Neutrophils, POST Within Below [N=53;45] | 4 | 4 | | |
| Neutrophils, POST Within Within [N=53;45] | 43 | 35 | | |
| Neutrophils, POST Within Above [N=53;45] | 6 | 6 | | |
| Neutrophils, POST Above Unknown [N=4;6] | 0 | 0 | | |
| Neutrophils, POST Above Below [N=4;6] | 0 | 0 | | |
| Neutrophils, POST Above Within [N=4;6] | 2 | 3 | | |
| Neutrophils, POST Above Above [N=4;6] | 2 | 3 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with clinically relevant abnormalities in biochemical and haematological parameters

| | |
|-----------------|---|
| End point title | Number of subjects with clinically relevant abnormalities in biochemical and haematological parameters ^[6] |
|-----------------|---|

End point description:

The parameters assessed were both biochemical (alanine aminotransferase = ALAT, creatinine = CREA, urea nitrogen = BUN) and haematological (basophils = BAS, eosinophils = EOS, red blood cells = RBC, hematocrit = HCT, hemoglobin, leukocytes [white blood cells] = WBC, lymphocytes, monocytes, neutrophils and platelets). Results were split into 2 outcomes due to the table size. Note that "99999" is a placeholder value since the number of subjects the respective categories was 0, hence the statistical analysis could not be performed.

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

End point timeframe:

42 days post dose 1 (PRE) and at 30 days post dose 2 (POST)

Notes:

[6] - 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 analysis was descriptive, hence no statistical analyses are available.

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|---|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 61 | 64 | | |
| Units: Subjects | | | | |
| Platelets, PRE Unknown Unknown [N=3;0] | 0 | 99999 | | |
| Platelets, PRE Unknown Below [N=3;0] | 0 | 99999 | | |
| Platelets, PRE Unknown Within [N=3;0] | 2 | 99999 | | |
| Platelets, PRE Unknown Above [N=3;0] | 1 | 99999 | | |
| Platelets, PRE Below Unknown [N=0;2] | 99999 | 0 | | |
| Platelets, PRE Below Below [N=0;2] | 99999 | 0 | | |
| Platelets, PRE Below Within [N=0;2] | 99999 | 2 | | |
| Platelets, PRE Below Above [N=0;2] | 99999 | 0 | | |
| Platelets, PRE Within Unknown [N=60;58] | 0 | 0 | | |
| Platelets, PRE Within Below [N=60;58] | 0 | 0 | | |
| Platelets, PRE Within Within [N=60;58] | 53 | 54 | | |
| Platelets, PRE Within Above [N=60;58] | 7 | 4 | | |
| Platelets, PRE Above Unknown [N=9;13] | 0 | 0 | | |
| Platelets, PRE Above Below [N=9;13] | 0 | 0 | | |
| Platelets, PRE Above Within [N=9;13] | 3 | 8 | | |
| Platelets, PRE Above Above [N=9;13] | 6 | 5 | | |
| Platelets, POST Unknown Unknown [N=3;0] | 0 | 99999 | | |
| Platelets, POST Unknown Below [N=3;0] | 0 | 99999 | | |

| | | | | |
|--|-------|-------|--|--|
| Platelets, POST Unknown Within [N=3;0] | 2 | 99999 | | |
| Platelets, POST Unknown Above [N=3;0] | 1 | 99999 | | |
| Platelets, POST Below Unknown [N=0;2] | 99999 | 0 | | |
| Platelets, POST Below Below [N=0;2] | 99999 | 0 | | |
| Platelets, POST Below Within [N=0;2] | 99999 | 2 | | |
| Platelets, POST Below Above [N=0;2] | 99999 | 0 | | |
| Platelets, POST Within Unknown [N=61;57] | 0 | 0 | | |
| Platelets, POST Within Below [N=61;57] | 0 | 0 | | |
| Platelets, POST Within Within [N=61;57] | 58 | 56 | | |
| Platelets, POST Within Above [N=61;57] | 3 | 1 | | |
| Platelets, POST Above Unknown [N=10;13] | 0 | 0 | | |
| Platelets, POST Above Below [N=10;13] | 0 | 0 | | |
| Platelets, POST Above Within [N=10;13] | 6 | 7 | | |
| Platelets, POST Above Above [N=10;13] | 4 | 6 | | |
| BUN, PRE Unknown Unknown [N=2;1] | 0 | 0 | | |
| BUN, PRE Unknown Below [N=2;1] | 0 | 0 | | |
| BUN, PRE Unknown Within [N=2;1] | 2 | 1 | | |
| BUN, PRE Unknown Above [N=2;1] | 0 | 0 | | |
| BUN, PRE Below Unknown [N=12;4] | 0 | 0 | | |
| BUN, PRE Below Below [N=12;4] | 4 | 1 | | |
| BUN, PRE Below Within [N=12;4] | 8 | 3 | | |
| BUN, PRE Below Above [N=12;4] | 0 | 0 | | |
| BUN, PRE Within Unknown [N=57;64] | 0 | 0 | | |
| BUN, PRE Within Below [N=57;64] | 2 | 7 | | |
| BUN, PRE Within Within [N=57;64] | 54 | 57 | | |
| BUN, PRE Within Above [N=57;64] | 1 | 0 | | |
| BUN, PRE Above Unknown [N=3;4] | 0 | 0 | | |
| BUN, PRE Above Below [N=3;4] | 0 | 0 | | |
| BUN, PRE Above Within [N=3;4] | 3 | 4 | | |
| BUN, PRE Above Above [N=3;4] | 0 | 0 | | |
| BUN, POST Unknown Unknown [N=2;1] | 0 | 0 | | |
| BUN, POST Unknown Below [N=2;1] | 0 | 0 | | |
| BUN, POST Unknown Within [N=2;1] | 2 | 1 | | |
| BUN, POST Unknown Above [N=2;1] | 0 | 0 | | |
| BUN, POST Below Unknown [N=12;4] | 0 | 0 | | |
| BUN, POST Below Below [N=12;4] | 5 | 0 | | |
| BUN, POST Below Within [N=12;4] | 7 | 4 | | |
| BUN, POST Below Above [N=12;4] | 0 | 0 | | |
| BUN, POST Within Unknown [N=55;63] | 0 | 0 | | |
| BUN, POST Within Below [N=55;63] | 3 | 10 | | |
| BUN, POST Within Within [N=55;63] | 52 | 53 | | |
| BUN, POST Within Above [N=55;63] | 0 | 0 | | |
| BUN, POST Above Unknown [N=3;4] | 0 | 0 | | |
| BUN, POST Above Below [N=3;4] | 0 | 0 | | |
| BUN, POST Above Within [N=3;4] | 3 | 4 | | |
| BUN, POST Above Above [N=3;4] | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with serious adverse events (SAEs)

| | |
|-----------------|--|
| End point title | Number of subjects with serious adverse events (SAEs) ^[7] |
|-----------------|--|

End point description:

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

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

End point timeframe:

From first vaccination to one month after the last vaccine dose (from Day 0 up to Month 7)

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: This analysis was descriptive, hence no statistical analyses are available.

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|-----------------------------|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 74 | 74 | | |
| Units: Subjects | 0 | 2 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with AEs and SAEs leading to withdrawal

| | |
|-----------------|---|
| End point title | Number of subjects with AEs and SAEs leading to withdrawal ^[8] |
|-----------------|---|

End point description:

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

End point timeframe:

From first vaccination to one month after the last vaccine dose (from Day 0 up to Month 7)

Notes:

[8] - 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 analysis was descriptive, hence no statistical analyses are available.

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|-----------------------------|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 74 | 74 | | |
| Units: Subjects | 0 | 2 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with potential immune-mediated diseases (pIMDs)

| | |
|-----------------|---|
| End point title | Number of subjects with potential immune-mediated diseases (pIMDs) ^[9] |
|-----------------|---|

End point description:

Potential immune-mediated diseases (pIMDs) are a subset of AEs that include autoimmune diseases and other inflammatory and/or neurologic disorders of interest which may or may not have an autoimmune aetiology

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

End point timeframe:

From first vaccination to one month after the last vaccine dose (from Day 0 up to Month 7)

Notes:

[9] - 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 analysis was descriptive, hence no statistical analyses are available.

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|-----------------------------|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 74 | 74 | | |
| Units: Subjects | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with medically significant conditions (MSCs)

| | |
|-----------------|---|
| End point title | Number of subjects with medically significant conditions (MSCs) ^[10] |
|-----------------|---|

End point description:

MSCs include AEs prompting emergency room or physician visits that are not related to common diseases or routine visits for physical examination or vaccination, or serious adverse events (SAEs) that are not related to common diseases. Common diseases include upper respiratory infections, sinusitis, pharyngitis, gastroenteritis, urinary tract infections, cervico-vaginal yeast infections, menstrual cycle abnormalities and injury.

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

End point timeframe:

From first vaccination to one month after the last vaccine dose (from Day 0 up to Month 7)

Notes:

[10] - 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 analysis was descriptive, hence no statistical analyses are available.

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|-----------------------------|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 74 | 74 | | |
| Units: Subjects | 38 | 28 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of serconverted subjects for anti-HPV-16/18

| | |
|-----------------|--|
| End point title | Number of serconverted subjects for anti-HPV-16/18 ^[11] |
|-----------------|--|

End point description:

A seroconverted subject was defined as a vaccinated subject who had either a pre-vaccination titer <1:10 and a post-vaccination titer ≥1:40 or a pre-vaccination titer ≥1:10 and at least a four-fold increase in post-vaccination titer.

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

End point timeframe:

One month after the last dose of study vaccine (Month 7)

Notes:

[11] - 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 analysis was descriptive, hence no statistical analyses are available.

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|-----------------------------|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 65 | 44 | | |
| Units: Subjects | | | | |
| HPV-16 | 65 | 1 | | |
| HPV-18 | 63 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Anti-HPV-16/18 antibody concentrations

| | |
|-----------------|--|
| End point title | Anti-HPV-16/18 antibody concentrations ^[12] |
|-----------------|--|

End point description:

Antibody concentrations were assessed by Enzyme-linked-Immunosorbent Assay (ELISA) and expressed as geometric mean titers (GMTs) in ELISA units per milliliter (EU/mL).

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

End point timeframe:

One month after the last dose of study vaccine (Month 7)

Notes:

[12] - 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 analysis was descriptive, hence no statistical analyses are available.

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|--|---------------------------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 65 | 45 | | |
| Units: EU/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| HPV-16 | 19677.4 (16463.7 to 23518.4) | 10.9 (8.9 to 13.4) | | |
| HPV-18 | 10509.1 (8818.9 to 12523.2) | 9.6 (8.4 to 11) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects seroconverted for anti-HPV-16/18 antibodies

| | |
|-----------------|--|
| End point title | Number of subjects seroconverted for anti-HPV-16/18 antibodies |
|-----------------|--|

End point description:

Seroconversion is defined as the appearance of antibodies (i.e. titre greater than or equal to the cut-off value) in the serum of subjects seronegative before vaccination. Values for Month 7 were primary outcomes and presented as such. Values past month 7 were not available at the time of posting this record and will be added once validated results become available.

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

End point timeframe:

At Day 0, Month 7 and Month 12

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|-----------------------------|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 65 | 45 | | |
| Units: Subjects | | | | |
| HPV-16, Day 0 | 0 | 1 | | |
| HPV-18, Day 0 | 2 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-HPV-16/18 antibody concentrations

| | |
|-----------------|--|
| End point title | Anti-HPV-16/18 antibody concentrations |
|-----------------|--|

End point description:

Antibody concentrations were calculated as geometric mean concentrations (GMCs), assessed by ELISA for the respective groups and expressed as ELISA units per milliliter (EU/mL). Values for Month 7 were primary outcomes and presented as such. Values past month 7 were not available at the time of posting this record and will be added once validated results become available.

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

End point timeframe:

At Day 0, Month 7 and Month 12

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|--|------------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 65 | 45 | | |
| Units: EU/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| HPV-16, Day 0 | 9.5 (9.5 to 9.5) | 10.3 (8.8 to 12.1) | | |
| HPV-18, Day 0 | 9.2 (8.9 to 9.6) | 9 (9 to 9) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with potential immune-mediated diseases (pIMDs)

| | |
|-----------------|--|
| End point title | Number of subjects with potential immune-mediated diseases (pIMDs) |
|-----------------|--|

End point description:

Potential immune-mediated diseases (pIMDs) are a subset of AEs that include autoimmune diseases and other inflammatory and/or neurologic disorders of interest which may or may not have an autoimmune aetiology

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

End point timeframe:

From first vaccination to 6 months after the last vaccine dose (from Day 0 up to Month 12)

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|-----------------------------|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 74 | 74 | | |
| Units: Subjects | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with medically significant conditions (MSCs)

| | |
|-----------------|---|
| End point title | Number of subjects with medically significant conditions (MSCs) |
|-----------------|---|

End point description:

MSCs include AEs prompting emergency room or physician visits that are not related to common diseases or routine visits for physical examination or vaccination, or serious adverse events (SAEs) that are not related to common diseases. Common diseases include upper respiratory infections, sinusitis, pharyngitis, gastroenteritis, urinary tract infections, cervico-vaginal yeast infections, menstrual cycle abnormalities and injury.

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

End point timeframe:

From first vaccination to 6 months after the last vaccine dose (from Day 0 up to Month 12)

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|-----------------------------|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 74 | 74 | | |
| Units: Subjects | 38 | 28 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events (SAEs)

| | |
|-----------------|---|
| End point title | Number of subjects with serious adverse events (SAEs) |
|-----------------|---|

End point description:

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

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

End point timeframe:

From first vaccination to 6 months after the last vaccine dose (from Day 0 up to Month 12)

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|-----------------------------|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 74 | 74 | | |
| Units: Subjects | 1 | 2 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting the intake of concomitant medication

| | |
|-----------------|---|
| End point title | Number of subjects reporting the intake of concomitant medication |
|-----------------|---|

End point description:

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

End point timeframe:

During the 43-day period (Days 0-42) following vaccination on Day 0 and during the 30-day period (Days 0-29) following vaccination at Month 6

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|--|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 74 | 74 | | |
| Units: Subjects | | | | |
| Any medication, Dose 1 (N=74,74) | 43 | 36 | | |
| Any antipyretic, Dose 1 (N=74,74) | 27 | 22 | | |
| Prophylactic antipyretic, Dose 1 (N=74,74) | 0 | 0 | | |
| Any antibiotic, Dose 1 (N=74,74) | 17 | 10 | | |
| Any medication, Dose 2 (N=74,71) | 19 | 23 | | |
| Any antipyretic, Dose 2 (N=74,71) | 10 | 8 | | |
| Prophylactic antipyretic, Dose 2 (N=74,71) | 0 | 0 | | |
| Any antibiotic, Dose 2 (N=74,71) | 6 | 6 | | |
| Any medication, Accross doses (N=74,74) | 49 | 43 | | |
| Any antipyretic, Accross doses (N=74,74) | 30 | 25 | | |
| Prophylactic antipyretic, Accross doses (N=74,74) | 0 | 0 | | |
| Any antibiotic, Accross doses (N=74,74) | 20 | 15 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: The number of subjects completing the vaccination schedule in all groups.

| | |
|-----------------|---|
| End point title | The number of subjects completing the vaccination schedule in all groups. |
|-----------------|---|

End point description:

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

End point timeframe:

From first vaccination to the last vaccine dose (from Day 0 up to Month 6)

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|-----------------------------|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 74 | 74 | | |
| Units: Subjects | | | | |
| Subjects receiving 1 dose | 0 | 3 | | |
| Subjects receiving 2 doses | 74 | 71 | | |
| Subjects receiving any dose | 74 | 74 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with of AEs/SAEs leading to withdrawal

| | |
|------------------------|---|
| End point title | Number of subjects with of AEs/SAEs leading to withdrawal |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| From Day 0 to Month 12 | |

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|-----------------------------|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 74 | 74 | | |
| Units: Subjects | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: The number of subjects with solicited fever, measles/rubella-like rash, parotid gland swelling and signs of meningism, including febrile convulsion

| | |
|---|---|
| End point title | The number of subjects with solicited fever, measles/rubella-like rash, parotid gland swelling and signs of meningism, including febrile convulsion |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| During the 43-day period (Days 0-42) following vaccination on Day 0 | |

| End point values | Cervarix Group | Priorix + Infanrix Group | | |
|-----------------------------------|-----------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 74 | 74 | | |
| Units: Subjects | | | | |
| Fever $\geq 37.5^{\circ}\text{C}$ | 30 | 26 | | |
| Fever $> 39.0^{\circ}\text{C}$ | 7 | 2 | | |
| Related Fever | 6 | 7 | | |
| Any rash | 1 | 1 | | |
| Rash with fever | 0 | 0 | | |
| Grade 3 rash | 0 | 0 | | |
| Related rash | 1 | 1 | | |
| Any Parotid gland swelling | 0 | 0 | | |
| Any Signs of Meningism | 0 | 1 | | |
| Grade 3 Signs of Meningism | 0 | 0 | | |
| Related Signs of Meningism | 0 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms: during the 7-day (Days 0-6) post-each dose

Unsolicited adverse events: within the 30-day (Days 0-29) post-each dose

Serious adverse events: from Day 0 up to Month 12

Adverse event reporting additional description:

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

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 18.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|----------------|
| Reporting group title | Cervarix Group |
|-----------------------|----------------|

Reporting group description:

Subjects aged 4-6 years receiving 2 doses of Cervarix vaccine at Day 0 and Month 6

| | |
|-----------------------|--------------------------|
| Reporting group title | Priorix + Infanrix Group |
|-----------------------|--------------------------|

Reporting group description:

Subjects aged 4-6 years receiving 1 dose of Priorix vaccine at Day 0 and 1 dose of Infanrix vaccine at Month 6

| Serious adverse events | Cervarix Group | Priorix + Infanrix Group | |
|---|----------------|--------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 74 (1.35%) | 2 / 74 (2.70%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Infections and infestations | | | |
| Abscess limb | | | |
| subjects affected / exposed | 0 / 74 (0.00%) | 1 / 74 (1.35%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 74 (1.35%) | 1 / 74 (1.35%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |

| | | | |
|---|----------------|----------------|--|
| subjects affected / exposed | 0 / 74 (0.00%) | 1 / 74 (1.35%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Cervarix Group | Priorix + Infanrix Group | |
|---|------------------|--------------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 54 / 74 (72.97%) | 40 / 74 (54.05%) | |
| General disorders and administration site conditions | | | |
| Pain | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 54 / 74 (72.97%) | 40 / 74 (54.05%) | |
| occurrences (all) | 54 | 40 | |
| Redness | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 18 / 74 (24.32%) | 18 / 74 (24.32%) | |
| occurrences (all) | 18 | 18 | |
| Swelling | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 19 / 74 (25.68%) | 18 / 74 (24.32%) | |
| occurrences (all) | 19 | 18 | |
| Arthralgia | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 13 / 74 (17.57%) | 11 / 74 (14.86%) | |
| occurrences (all) | 13 | 11 | |
| Drowsiness | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 16 / 74 (21.62%) | 15 / 74 (20.27%) | |
| occurrences (all) | 16 | 15 | |
| Fever/(Axillary) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 12 / 74 (16.22%) | 17 / 74 (22.97%) | |
| occurrences (all) | 12 | 17 | |

| | | | |
|--|------------------|------------------|--|
| Fatigue | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 15 / 74 (20.27%) | 10 / 74 (13.51%) | |
| occurrences (all) | 15 | 10 | |
| Gastrointestinal | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 11 / 74 (14.86%) | 16 / 74 (21.62%) | |
| occurrences (all) | 11 | 16 | |
| Headache | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 18 / 74 (24.32%) | 25 / 74 (33.78%) | |
| occurrences (all) | 18 | 25 | |
| Irritability / fussiness | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 22 / 74 (29.73%) | 19 / 74 (25.68%) | |
| occurrences (all) | 22 | 19 | |
| Myalgia | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 21 / 74 (28.38%) | 14 / 74 (18.92%) | |
| occurrences (all) | 21 | 14 | |
| Loss of appetite | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 21 / 74 (28.38%) | 13 / 74 (17.57%) | |
| occurrences (all) | 21 | 13 | |
| Rash | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 6 / 74 (8.11%) | 5 / 74 (6.76%) | |
| occurrences (all) | 6 | 5 | |
| Urticaria | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 10 / 74 (13.51%) | 7 / 74 (9.46%) | |
| occurrences (all) | 10 | 7 | |
| Infections and infestations | | | |

| | | | |
|-----------------------------|------------------|------------------|--|
| Nasopharyngitis | | | |
| subjects affected / exposed | 21 / 74 (28.38%) | 23 / 74 (31.08%) | |
| occurrences (all) | 21 | 23 | |
| Pharyngitis | | | |
| subjects affected / exposed | 4 / 74 (5.41%) | 3 / 74 (4.05%) | |
| occurrences (all) | 4 | 3 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 3 / 74 (4.05%) | 5 / 74 (6.76%) | |
| occurrences (all) | 3 | 5 | |

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