



Clinical trial results:

An open-label primary vaccination study to assess the safety and reactogenicity of GlaxoSmithKline Biologicals' combined diphtheria-tetanus-acellular pertussis-inactivated poliovirus-Haemophilus influenzae type b (DTPa-IPV/Hib) vaccine administered as a three-dose primary vaccination course at 2-3-4 or 3-4-5 months of age in healthy infants in China.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2015-001513-27 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 12 April 2010 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v1 |
| This version publication date | 18 April 2016 |
| First version publication date | 04 July 2015 |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 112065 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00964028 |
| 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, 44 2089904466, GSKClinicalSupportHD@gsk.com |
| Scientific contact | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|---------------|
| Analysis stage | Final |
| Date of interim/final analysis | 23 July 2010 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 12 April 2010 |
| Global end of trial reached? | Yes |
| Global end of trial date | 12 April 2010 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and reactogenicity of the study vaccine administered as a three-dose primary vaccination course.

Protection of trial subjects:

All subjects were supervised closely for at least 30 minutes following vaccination 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. Subjects were followed-up from the time the subject consents to participate in the study until she/he is discharged.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 01 December 2009 |
| 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 | China: 50 |
| Worldwide total number of subjects | 50 |
| 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) | 50 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

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

Period 1

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

Arms

| | |
|------------------------------|--------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Infanrix-IPV/Hib Group A |

Arm description: -

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Infanrix™-IPV/Hib |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

The vaccine was administered intramuscularly into the upper right side of the thigh, at 2, 3, 4 months of age.

| | |
|------------------|--------------------------|
| Arm title | Infanrix-IPV/Hib Group B |
|------------------|--------------------------|

Arm description: -

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Infanrix™-IPV/Hib |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

The vaccine was administered intramuscularly into the upper right side of the thigh, at 3, 4, 5 months of age.

| Number of subjects in period 1 | Infanrix-IPV/Hib Group A | Infanrix-IPV/Hib Group B |
|--------------------------------|--------------------------|--------------------------|
| Started | 25 | 25 |
| Completed | 25 | 24 |
| Not completed | 0 | 1 |
| Consent withdrawn by subject | - | 1 |

Baseline characteristics

Reporting groups

| | |
|--------------------------------|--------------------------|
| Reporting group title | Infanrix-IPV/Hib Group A |
| Reporting group description: - | |
| Reporting group title | Infanrix-IPV/Hib Group B |
| Reporting group description: - | |

| Reporting group values | Infanrix-IPV/Hib Group A | Infanrix-IPV/Hib Group B | Total |
|--|--------------------------|--------------------------|-------|
| Number of subjects | 25 | 25 | 50 |
| Age categorical Units: Subjects | | | |
| In utero | | | 0 |
| Preterm newborn infants (gestational age < 37 wks) | | | 0 |
| Newborns (0-27 days) | | | 0 |
| Infants and toddlers (28 days-23 months) | | | 0 |
| Children (2-11 years) | | | 0 |
| Adolescents (12-17 years) | | | 0 |
| Adults (18-64 years) | | | 0 |
| From 65-84 years | | | 0 |
| 85 years and over | | | 0 |
| Age continuous Units: weeks | | | |
| arithmetic mean | 10.1 | 14.2 | |
| standard deviation | ± 1.36 | ± 1.18 | - |
| Gender categorical Units: Subjects | | | |
| Female | 7 | 11 | 18 |
| Male | 18 | 14 | 32 |

End points

End points reporting groups

| | |
|--------------------------------|--------------------------|
| Reporting group title | Infanrix-IPV/Hib Group A |
| Reporting group description: - | |
| Reporting group title | Infanrix-IPV/Hib Group B |
| Reporting group description: - | |

Primary: Number of subjects with any solicited local symptoms

| | |
|------------------------|---|
| End point title | Number of subjects with any solicited local symptoms ^[1] |
| End point description: | |

| | |
|---|---------|
| End point type | Primary |
| End point timeframe: | |
| During the 4-day (Day 0-Day 3) follow-up period | |

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | Infanrix- IPV/Hib Group A | Infanrix- IPV/Hib Group B | | |
|-------------------------------------|---------------------------------|---------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 25 | 25 | | |
| Units: Subjects | | | | |
| Any pain Dose 1 [N=25;25] | 4 | 2 | | |
| Any redness Dose 1 [N=25;25] | 2 | 0 | | |
| Any swelling Dose 1 [N=25;25] | 1 | 0 | | |
| Any pain Dose 2 [N=25;24] | 1 | 1 | | |
| Any redness Dose 2 [N=25;24] | 2 | 0 | | |
| Any swelling Dose 2 [N=25;24] | 1 | 0 | | |
| Any pain Dose 3 [N=25;24] | 2 | 1 | | |
| Any redness Dose 3 [N=25;24] | 2 | 0 | | |
| Any swelling Dose 3 [N=25;24] | 0 | 0 | | |
| Any pain Across doses [N=25;25] | 4 | 3 | | |
| Any redness Across doses [N=25;25] | 4 | 0 | | |
| Any swelling Across doses [N=25;25] | 2 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any solicited general symptoms

| | |
|-----------------|---|
| End point title | Number of subjects with any solicited general symptoms ^[2] |
|-----------------|---|

End point description:

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

End point timeframe:

During the 4-day (Day 0-Day 3) follow-up period

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | Infanrix- IPV/Hib Group A | Infanrix- IPV/Hib Group B | | |
|--|---------------------------------|---------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 25 | 25 | | |
| Units: Subjects | | | | |
| Any Drowsiness Dose 1 [N=25;25] | 9 | 1 | | |
| Any Irritability Dose 1 [N=25;25] | 9 | 5 | | |
| Any Loss of appetite Dose 1 [N=25;25] | 7 | 1 | | |
| Any Fever Dose 1 [N=25;25] | 8 | 8 | | |
| Any Drowsiness Dose 2 [N=25;24] | 3 | 5 | | |
| Any Irritability Dose 2 [N=25;24] | 6 | 3 | | |
| Any Loss of appetite Dose 2 [N=25;24] | 3 | 3 | | |
| Any Fever Dose 2 [N=25;24] | 5 | 5 | | |
| Any Drowsiness Dose 3 [N=25;24] | 2 | 0 | | |
| Any Irritability Dose 3 [N=25;24] | 5 | 4 | | |
| Any Loss of appetite Dose 3 [N=25;24] | 3 | 1 | | |
| Any Fever Dose 3 [N=25;24] | 7 | 3 | | |
| Any Drowsiness Across doses [N=25;25] | 12 | 5 | | |
| Any Irritability Across doses [N=25;25] | 15 | 8 | | |
| Any Loss of appetite Across doses [N=25;25] | 9 | 4 | | |
| Any Fever Across doses [N=25;25] | 13 | 12 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with unsolicited adverse events (AEs)

| | |
|-----------------|---|
| End point title | Number of subjects with unsolicited adverse events (AEs) ^[3] |
|-----------------|---|

End point description:

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

End point timeframe:

During the 31-day (Day 0–30) follow-up period

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was

performed.

| End point values | Infanrix- IPV/Hib Group A | Infanrix- IPV/Hib Group B | | |
|-----------------------------|---------------------------------|---------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 25 | 25 | | |
| Units: Subjects | | | | |
| AEs | 16 | 1 | | |

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) ^[4] |
|-----------------|--|

End point description:

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

End point timeframe:

During the whole study period

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | Infanrix- IPV/Hib Group A | Infanrix- IPV/Hib Group B | | |
|-----------------------------|---------------------------------|---------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 25 | 25 | | |
| Units: Subjects | | | | |
| SAEs | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

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 | 13.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--------------------------|
| Reporting group title | Infanrix-IPV/Hib Group A |
|-----------------------|--------------------------|

Reporting group description: -

| | |
|-----------------------|--------------------------|
| Reporting group title | Infanrix-IPV/Hib Group B |
|-----------------------|--------------------------|

Reporting group description: -

| Serious adverse events | Infanrix-IPV/Hib Group A | Infanrix-IPV/Hib Group B | |
|---|--------------------------|--------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 25 (0.00%) | 0 / 25 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |

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

| Non-serious adverse events | Infanrix-IPV/Hib Group A | Infanrix-IPV/Hib Group B | |
|---|--------------------------|--------------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 25 / 25 (100.00%) | 25 / 25 (100.00%) | |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 5 / 25 (20.00%) | 0 / 25 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Pain | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 4 / 25 (16.00%) | 3 / 25 (12.00%) | |
| occurrences (all) | 4 | 3 | |
| Redness | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|--|------------------|------------------|--|
| subjects affected / exposed | 4 / 25 (16.00%) | 0 / 25 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Swelling | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 2 / 25 (8.00%) | 0 / 25 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Drowsiness | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 12 / 25 (48.00%) | 5 / 25 (20.00%) | |
| occurrences (all) | 12 | 5 | |
| Irritability | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 15 / 25 (60.00%) | 8 / 25 (32.00%) | |
| occurrences (all) | 15 | 8 | |
| Loss of appetite | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 9 / 25 (36.00%) | 4 / 25 (16.00%) | |
| occurrences (all) | 9 | 4 | |
| Fever | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 13 / 25 (52.00%) | 12 / 25 (48.00%) | |
| occurrences (all) | 13 | 12 | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 4 / 25 (16.00%) | 0 / 25 (0.00%) | |
| occurrences (all) | 4 | 0 | |
| Infections and infestations | | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 10 / 25 (40.00%) | 1 / 25 (4.00%) | |
| occurrences (all) | 10 | 1 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 4 / 25 (16.00%) | 0 / 25 (0.00%) | |
| occurrences (all) | 4 | 0 | |

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