



## 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	v2
This version publication date	13 May 2018
First version publication date	04 July 2015
Version creation reason	<ul style="list-style-type: none"><li>• Correction of full data set</li></ul> Minor corrections of the full study results.

### Trial information

#### Trial identification

Sponsor protocol code	112065
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#### 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
<b>Arm title</b>	Infanrix-IPV/Hib Group A

Arm description:

Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 2, 3 and 4 months of age (M2-M3-M4), administered intramuscularly into the upper right side of the thigh.

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.

<b>Arm title</b>	Infanrix-IPV/Hib Group B
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Arm description:

Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 3, 4 and 5 months of age (M3-M4-M5), administered intramuscularly into the upper right side of the thigh.

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.

<b>Number of subjects in period 1</b>	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
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Reporting group description:

Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 2, 3 and 4 months of age (M2-M3-M4), administered intramuscularly into the upper right side of the thigh.

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

Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 3, 4 and 5 months of age (M3-M4-M5), administered intramuscularly into the upper right side of the thigh.

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
Race/Ethnicity			
Units: Subjects			
Asian-East Asian heritage	24	25	49
Asian-Japanese heritage	1	0	1

## End points

### End points reporting groups

Reporting group title	Infanrix-IPV/Hib Group A
Reporting group description: Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 2, 3 and 4 months of age (M2-M3-M4), administered intramuscularly into the upper right side of the thigh.	
Reporting group title	Infanrix-IPV/Hib Group B
Reporting group description: Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 3, 4 and 5 months of age (M3-M4-M5), administered intramuscularly into the upper right side of the thigh.	

### Primary: Number of subjects with any solicited local symptoms

End point title	Number of subjects with any solicited local symptoms <sup>[1]</sup>
End point description: Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of any local symptom regardless of intensity grade.	
End point type	Primary
End point timeframe: During the 4-day (Day 0-Day 3) follow-up period after each dose and across doses	

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 <sup>[2]</sup>
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End point description:

Assessed solicited general symptoms were drowsiness, irritability, loss of appetite and fever [defined as axillary temperature equal to or above 37.0 degrees Celsius (°C)]. Any = occurrence of any general symptom regardless of intensity grade or relationship to vaccination.

End point type	Primary
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End point timeframe:

During the 4-day (Day 0-Day 3) follow-up period after each dose and across doses

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) <sup>[3]</sup>
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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.

End point type	Primary
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End point timeframe:

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

Notes:

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

Justification: 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) <sup>[4]</sup>
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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
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End point timeframe:

During the whole study period (from Day 0 until Month 3 or Month 4)

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:

Solicited local and general symptoms: during the 4-day (Days 0-3) post-vaccination period. Unsolicited AEs: during the 31-day (Days 0-30) post-vaccination period. SAEs: during the entire study period (from Day 0 until Month 3/4).

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	13.0

### Reporting groups

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

Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 2, 3 and 4 months of age (M2-M3-M4), administered intramuscularly into the upper right side of the thigh.

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

Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 3, 4 and 5 months of age (M3-M4-M5), administered intramuscularly into the upper right side of the thigh.

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	23 / 25 (92.00%)	16 / 25 (64.00%)	
General disorders and administration site conditions			
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 25 (20.00%)	0 / 25 (0.00%)	
occurrences (all)	5	0	
Pain			

subjects affected / exposed occurrences (all)	4 / 25 (16.00%) 4	3 / 25 (12.00%) 3	
Redness subjects affected / exposed occurrences (all)	4 / 25 (16.00%) 4	0 / 25 (0.00%) 0	
Swelling subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	0 / 25 (0.00%) 0	
Drowsiness subjects affected / exposed occurrences (all)	12 / 25 (48.00%) 12	5 / 25 (20.00%) 5	
Irritability subjects affected / exposed occurrences (all)	15 / 25 (60.00%) 15	8 / 25 (32.00%) 8	
Loss of appetite subjects affected / exposed occurrences (all)	9 / 25 (36.00%) 9	4 / 25 (16.00%) 4	
Fever subjects affected / exposed occurrences (all)	13 / 25 (52.00%) 13	12 / 25 (48.00%) 12	
Gastrointestinal disorders Diarrhoea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	4 / 25 (16.00%) 4	0 / 25 (0.00%) 0	
Infections and infestations Upper respiratory tract infection alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	10 / 25 (40.00%) 10	1 / 25 (4.00%) 1	
Nasopharyngitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	4 / 25 (16.00%) 4	0 / 25 (0.00%) 0	



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported