

**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
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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
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]
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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.

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
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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: -

Reporting group title	Infanrix-IPV/Hib Group B
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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