



Clinical trial results:

An open-label primary vaccination study to assess the safety and reactogenicity of GlaxoSmithKline (GSK) Biologicals' Inactivated Poliomyelitis vaccine (IPV) Poliorix administered as a three-dose primary vaccination course at 2, 3 and 4 months of age in healthy infants in China

Summary

EudraCT number	2017-001607-80
Trial protocol	Outside EU/EEA
Global end of trial date	13 November 2009

Results information

Result version number	v1 (current)
This version publication date	05 January 2018
First version publication date	05 January 2018

Trial information

Trial identification

Sponsor protocol code	112581
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00937404
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut, 89, Rixensart, Belgium, 1330
Public contact	Clinical Disclosure Advisor, GlaxoSmithKline Biologicals, ((44)2089) 904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Disclosure Advisor, GlaxoSmithKline Biologicals, ((44)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	Final
Date of interim/final analysis	13 November 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 November 2009
Global end of trial reached?	Yes
Global end of trial date	13 November 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and reactogenicity of GSK Biologicals' Poliorix vaccine administered as a three-dose primary vaccination course

Protection of trial subjects:

All subjects will be observed closely for at least 30 minutes, with appropriate medical treatment readily available in case of a rare anaphylactic reaction following the administration of vaccines

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 August 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: 25
Worldwide total number of subjects	25
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)	25
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: -

Pre-assignment period milestones

Number of subjects started	25
Number of subjects completed	25

Period 1

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

Arms

Arm title	IPV Group
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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 Poliorix at 2 (Study Day 0, Visit 1), 3 (Study Month 1, Visit 2) and 4 (Study Month 2, Visit 3) months of age, administered intramuscularly into the upper right side of the thigh.

Arm type	Experimental
Investigational medicinal product name	Poliorix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

All subjects received three doses of Poliorix vaccine, administered intramuscularly into the upper right side of the thigh

Number of subjects in period 1	IPV Group
Started	25
Completed	23
Not completed	2
Consent withdrawn by subject	1
Protocol deviation	1

Baseline characteristics

Reporting groups

Reporting group title	IPV Group
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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 Poliorix at 2 (Study Day 0, Visit 1), 3 (Study Month 1, Visit 2) and 4 (Study Month 2, Visit 3) months of age, administered intramuscularly into the upper right side of the thigh.

Reporting group values	IPV Group	Total	
Number of subjects	25	25	
Age categorical Units: Subjects			
Age continuous Units: weeks arithmetic mean standard deviation	9.6 ± 1.38	-	
Gender categorical Units: Subjects			
Female	15	15	
Male	10	10	
Race/Ethnicity, Customized Units: Subjects			
Asian-Chinese Heritage	25	25	

End points

End points reporting groups

Reporting group title	IPV Group
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 Poliorix at 2 (Study Day 0, Visit 1), 3 (Study Month 1, Visit 2) and 4 (Study Month 2, Visit 3) months of age, administered intramuscularly into the upper right side of the thigh.	

Primary: Number of subjects reporting solicited local symptoms

End point title	Number of subjects reporting solicited local symptoms ^[1]
End point description:	
Solicited local symptoms assessed were pain, redness and swelling. Any = occurrence of the symptom irrespective of intensity grade. Grade 3 pain = cried when limb was moved/spontaneously painful. Grade 3 redness/swelling = redness/swelling spreading beyond 30 millimetres (mm) of injection site.	
End point type	Primary
End point timeframe:	
During the 4-day follow-up period after each dose of study vaccine.	

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 scope of this end point was descriptive, no statistical hypothesis test was performed.

End point values	IPV Group			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Participants				
Any Pain, Dose 1	1			
Grade 3 Pain, Dose 1	0			
Any Redness, Dose 1	2			
Grade 3 Redness, Dose 1	0			
Any Swelling, Dose 1	1			
Grade 3 Swelling, Dose 1	0			
Any Pain, Dose 2 (N=23)	2			
Grade 3 Pain, Dose 2 (N=23)	0			
Any Redness, Dose 2 (N=23)	1			
Grade 3 Redness, Dose 2 (N=23)	0			
Any Swelling, Dose 2 (N=23)	1			
Grade 3 Swelling, Dose 2 (N=23)	0			
Any Pain, Dose 3 (N=23)	1			
Grade 3 Pain, Dose 3 (N=23)	0			
Any Redness, Dose 3 (N=23)	0			
Grade 3 Redness, Dose 3 (N=23)	0			
Any Swelling, Dose 3 (N=23)	0			
Grade 3 Swelling, Dose 3 (N=23)	0			
Any Pain, Across doses	3			
Grade 3 Pain, Across doses	0			
Any Redness, Across doses	2			
Grade 3 Redness, Across doses	0			

Any Swelling, Across doses	2			
Grade 3 Swelling, Across doses	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects reporting solicited general symptoms

End point title	Number of subjects reporting solicited general symptoms ^[2]
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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 (\geq) 37.1 degrees Celsius ($^{\circ}$ C)]. Any = occurrence of symptom regardless of intensity grade of relationship to vaccination. Grade 3 drowsiness = drowsiness that prevented normal activity. Grade 3 irritability = crying that could not be comforted/prevented normal activity. Grade 3 loss of appetite = subject did not eat at all. Grade 3 fever = fever above ($>$) 39.0 $^{\circ}$ C. Related = symptom assessed by the investigator as related to vaccination.

End point type	Primary
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End point timeframe:

During the 4-day follow-up period after each dose of study vaccine.

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 scope of this end point was descriptive, no statistical hypothesis test was performed.

End point values	IPV Group			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Participants				
Any Drowsiness, Dose 1	7			
Grade 3 Drowsiness, Dose 1	0			
Related Drowsiness, Dose 1	7			
Any Irritability, Dose 1	10			
Grade 3 Irritability, Dose 1	0			
Related Irritability, Dose 1	10			
Any Loss of appetite, Dose 1	7			
Grade 3 Loss of appetite, Dose 1	0			
Related Loss of appetite, Dose 1	7			
Any Fever, Dose 1	8			
Grade 3 Fever, Dose 1	0			
Related Fever, Dose 1	6			
Any Drowsiness, Dose 2 (N=23)	2			
Grade 3 Drowsiness, Dose 2 (N=23)	0			
Related Drowsiness, Dose 2 (N=23)	2			
Any Irritability, Dose 2 (N=23)	7			
Grade 3 Irritability, Dose 2 (N=23)	0			
Related Irritability, Dose 2 (N=23)	6			
Any Loss of appetite, Dose 2 (N=23)	4			
Grade 3 Loss of appetite, Dose 2 (N=23)	0			
Related Loss of appetite, Dose 2 (N=23)	3			

Any Fever, Dose 2 (N=23)	3			
Grade 3 Fever, Dose 2 (N=23)	0			
Related Fever, Dose 2 (N=23)	3			
Any Drowsiness, Dose 3 (N=23)	3			
Grade 3 Drowsiness, Dose 3 (N=23)	0			
Related Drowsiness, Dose 3 (N=23)	1			
Any Irritability, Dose 3 (N=23)	7			
Grade 3 Irritability, Dose 3 (N=23)	2			
Related Irritability, Dose 3 (N=23)	3			
Any Loss of appetite, Dose 3 (N=23)	6			
Grade 3 Loss of appetite, Dose 3 (N=23)	0			
Related Loss of appetite, Dose 3 (N=23)	3			
Any Fever, Dose 3 (N=23)	4			
Grade 3 Fever, Dose 3 (N=23)	0			
Related Fever, Dose 3 (N=23)	2			
Any Drowsiness, Across doses	8			
Grade 3 Drowsiness, Across doses	0			
Related Drowsiness, Across doses	8			
Any Irritability, Across doses	14			
Grade 3 Irritability, Across doses	2			
Related Irritability, Across doses	12			
Any Loss of appetite, Across doses	9			
Grade 3 Loss of appetite, Across doses	0			
Related Loss of appetite, Across doses	8			
Any Fever, Across doses	12			
Grade 3 Fever, Across doses	0			
Related Fever, Across doses	9			

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects reporting unsolicited adverse events
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End point description:

Unsolicited AE covers any AE 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 = occurrence of any unsolicited symptom regardless of intensity grade or relation to vaccination.

End point type	Primary
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End point timeframe:

During the 31-days follow-up period after each dose of the study vaccine.

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 scope of this end point was descriptive, no statistical hypothesis test was performed.

End point values	IPV Group			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Participants				
Participants	15			

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects reporting serious adverse events (SAEs) ^[4]
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End point description:

SAEs assessed included any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity or was a congenital anomaly/birth defect in the offspring of a study subject.

End point type	Primary
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End point timeframe:

During the entire study period (from Dose 1 up to one month following last vaccine dose).

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 scope of this end point was descriptive, no statistical hypothesis test was performed.

End point values	IPV Group			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Participants				
Participants	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms: during 4-day post-vaccination period after each vaccine dose. Unsolicited AEs: during 31-day post-vaccination period after each vaccine dose. SAEs: during entire study period (from Dose 1 up to one month following last vaccine dose)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	12.1
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Reporting groups

Reporting group title	IPV Group
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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 Poliorix at 2 (Study Day 0, Visit 1), 3 (Study Month 1, Visit 2) and 4 (Study Month 2, Visit 3) months of age, administered intramuscularly into the upper right side of the thigh.

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

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	IPV Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 25 (80.00%)		
Nervous system disorders			
Somnolence			
subjects affected / exposed	8 / 25 (32.00%)		
occurrences (all)	12		
General disorders and administration site conditions			
Pain			
subjects affected / exposed	3 / 25 (12.00%)		
occurrences (all)	4		
Pyrexia			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Swelling</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>16 / 25 (64.00%)</p> <p>21</p> <p>2 / 25 (8.00%)</p> <p>2</p>		
<p>Eye disorders</p> <p>Conjunctivitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 25 (4.00%)</p> <p>1</p>		
<p>Gastrointestinal disorders</p> <p>Abdominal distension</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Diarrhoea</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Dyspepsia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 25 (4.00%)</p> <p>1</p> <p>5 / 25 (20.00%)</p> <p>7</p> <p>3 / 25 (12.00%)</p> <p>4</p>		
<p>Skin and subcutaneous tissue disorders</p> <p>Erythema</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>2 / 25 (8.00%)</p> <p>3</p>		
<p>Psychiatric disorders</p> <p>Irritability</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>14 / 25 (56.00%)</p> <p>24</p>		
<p>Infections and infestations</p> <p>Bronchitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Nasopharyngitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Skin infection</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 25 (4.00%)</p> <p>1</p> <p>4 / 25 (16.00%)</p> <p>9</p> <p>1 / 25 (4.00%)</p> <p>1</p>		

Upper respiratory tract infection subjects affected / exposed occurrences (all)	7 / 25 (28.00%) 8		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	9 / 25 (36.00%) 17		

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