



Clinical trial results:

An open-label study to assess the safety and reactogenicity of GlaxoSmithKline (GSK) Biologicals' Inactivated Poliomyelitis Vaccine (IPV) Poliorix administered as a booster dose at 18-24 months of age in healthy toddlers in China

Summary

EudraCT number	2017-001608-32
Trial protocol	Outside EU/EEA
Global end of trial date	03 August 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	112683
-----------------------	--------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00920439
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	03 August 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 August 2009
Global end of trial reached?	Yes
Global end of trial date	03 August 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 a booster dose of GSK Biologicals' IPV in toddlers

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	23 June 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:

Out of 26 subjects enrolled in the study, one did not receive any vaccination.

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	Poliorix Group
-----------	----------------

Arm description:

Healthy male or female subjects between, and including, 18 and 24 months of age, received a single booster dose of Poliorix vaccine that was administrated into the upper right thigh by intramuscular injection (IM).

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 a single booster dose of Poliorix vaccine

Number of subjects in period 1	Poliorix Group
Started	25
Completed	25

Baseline characteristics

Reporting groups

Reporting group title	Poliorix Group
-----------------------	----------------

Reporting group description:

Healthy male or female subjects between, and including, 18 and 24 months of age, received a single booster dose of Poliorix vaccine that was administrated into the upper right thigh by intramuscular injection (IM).

Reporting group values	Poliorix Group	Total	
Number of subjects	25	25	
Age categorical Units: Subjects			
Age continuous Units: months arithmetic mean standard deviation	20.3 ± 1.49	-	
Gender categorical Units: Subjects			
Female	13	13	
Male	12	12	

End points

End points reporting groups

Reporting group title	Poliorix Group
Reporting group description: Healthy male or female subjects between, and including, 18 and 24 months of age, received a single booster dose of Poliorix vaccine that was administrated into the upper right thigh by intramuscular injection (IM).	

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

End point title	Number of subjects with any and Grade 3 solicited local symptoms ^[1]
End point description: Assessed solicited local symptoms were pain, redness and swelling. Any = all reports of the specified symptom irrespective of intensity grade. Grade 3 pain = cried when limb was moved/spontaneously painful. Grade 3 redness/swelling = redness/swelling spreading beyond 30 millimeters (mm) of injection site.	
End point type	Primary
End point timeframe: During the 4-day (Days 0-3) post-vaccination 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 scope of this end point was descriptive, no statistical hypothesis test was performed.	

End point values	Poliorix Group			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Subjects				
Any Pain	4			
Grade 3 Pain	0			
Any Redness	5			
Grade 3 Redness	0			
Any Swelling	3			
Grade 3 Swelling	0			

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 temperature [defined as axillary temperature equal to or above (\geq) 37.1 degrees Celsius ($^{\circ}$ C)], drowsiness, irritability and loss of appetite. Any = all reports of the specified symptom irrespective of intensity grade and 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 °C. Related = symptom assessed by the investigator as related to the vaccination.

End point type	Primary
End point timeframe:	
During the 4-day (Days 0-3) post-vaccination 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 scope of this end point was descriptive, no statistical hypothesis test was performed.

End point values	Poliorix Group			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Subjects				
Any Drowsiness	3			
Grade 3 Drowsiness	0			
Related Drowsiness	3			
Any Irritability	5			
Grade 3 Irritability	0			
Related Irritability	3			
Any Loss of appetite	3			
Grade 3 Loss of appetite	0			
Related Loss of appetite	2			
Any Temperature	6			
Grade 3 Temperature	0			
Related Temperature	5			

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with any, Grade 3 and related unsolicited 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 31-day (Days 0-30) post-vaccination 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 scope of this end point was descriptive, no statistical hypothesis test was performed.

End point values	Poliorix Group			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Subjects				
Any AE(s)	10			
Grade 3 AE(s)	0			
Related AE(s)	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) ^[4]
-----------------	--

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:

During the entire study period (from Day 0 to Month 1)

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	Poliorix Group			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Subjects				
Subjects	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited 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 up to Month 1).

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
Dictionary version	12.0

Reporting groups

Reporting group title	Poliorix Group
-----------------------	----------------

Reporting group description:

Healthy male or female subjects between, and including, 18 and 24 months of age, received a single booster dose of Poliorix vaccine that was administrated into the upper right thigh by intramuscular injection (IM).

Serious adverse events	Poliorix 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: 5 %

Non-serious adverse events	Poliorix Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 25 (56.00%)		
Nervous system disorders			
Somnolence			
subjects affected / exposed	3 / 25 (12.00%)		
occurrences (all)	3		
General disorders and administration site conditions			
Pain			
subjects affected / exposed	4 / 25 (16.00%)		
occurrences (all)	4		
Pyrexia			

subjects affected / exposed occurrences (all)	7 / 25 (28.00%) 10		
Swelling subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 3		
Skin and subcutaneous tissue disorders Erythema subjects affected / exposed occurrences (all)	5 / 25 (20.00%) 5		
Psychiatric disorders Irritability subjects affected / exposed occurrences (all)	5 / 25 (20.00%) 5		
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 4		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 4		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 3		

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