



Clinical trial results:

An open, multicentric, post-marketing surveillance (PMS) study to assess the safety and reactogenicity of GlaxoSmithKline Biologicals' DTPa-IPV/Hib vaccine administered at 3, 4, 5 and 18 months of age, in healthy infants.

Summary

EudraCT number	2015-001512-35
Trial protocol	Outside EU/EEA
Global end of trial date	23 August 2007

Results information

Result version number	v2 (current)
This version publication date	12 May 2018
First version publication date	09 July 2015
Version creation reason	• Correction of full data set - Minor corrections of the full study results.

Trial information

Trial identification

Sponsor protocol code	100917
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00325156
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, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 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	12 August 2008
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 August 2007
Global end of trial reached?	Yes
Global end of trial date	23 August 2007
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 DTPa-IPV/Hib vaccine.

Protection of trial subjects:

The vaccines were closely observed for at least 30 minutes following the administration of the study vaccine, with appropriate medical treatment readily available in case of a rare anaphylactic reaction.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 November 2004
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	Singapore: 2590
Worldwide total number of subjects	2590
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)	2590
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	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Infanrix-IPV+Hib Group
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Arm description:

Healthy male or female subjects between and including 11 to 17 weeks of age at the time of first vaccination, who previously participated in a human rotavirus (HRV) study (444563/028), received 3 primary doses and one booster dose of Infanrix-IPV/Hib vaccine at 3,4 and 5 months of age and 18 months of age, respectively, administered intramuscularly into the anterolateral thigh. Subjects also received 2 oral doses of Rotarix (HRV) vaccine or placebo, at 3 and 4 months of age.

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:

Subjects received 3 primary doses and 1 booster dose which were administered intramuscularly into anterolateral thigh.

Investigational medicinal product name	Rotarix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution in single-dose container
Routes of administration	Oral use

Dosage and administration details:

Subjects received two oral doses of Rotarix at 3 and 4 months of age.

Number of subjects in period 1	Infanrix-IPV+Hib Group
Started	2590
Completed	2478
Not completed	112
Consent withdrawn by subject	31
Adverse event, non-fatal	3

Lost to follow-up (complete vaccination)	41
Migrated/moved from study area	12
Unspecified	1
Lost to follow-up (Incomplete vaccination)	16
Protocol deviation	8

Baseline characteristics

Reporting groups

Reporting group title	Infanrix-IPV+Hib Group
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Reporting group description:

Healthy male or female subjects between and including 11 to 17 weeks of age at the time of first vaccination, who previously participated in a human rotavirus (HRV) study (444563/028), received 3 primary doses and one booster dose of Infanrix-IPV/Hib vaccine at 3,4 and 5 months of age and 18 months of age, respectively, administered intramuscularly into the anterolateral thigh. Subjects also received 2 oral doses of Rotarix (HRV) vaccine or placebo, at 3 and 4 months of age.

Reporting group values	Infanrix-IPV+Hib Group	Total	
Number of subjects	2590	2590	
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	13.3		
standard deviation	± 0.87	-	
Gender categorical			
Units: Subjects			
Female	1245	1245	
Male	1345	1345	

End points

End points reporting groups

Reporting group title	Infanrix-IPV+Hib Group
Reporting group description:	
Healthy male or female subjects between and including 11 to 17 weeks of age at the time of first vaccination, who previously participated in a human rotavirus (HRV) study (444563/028), received 3 primary doses and one booster dose of Infanrix-IPV/Hib vaccine at 3,4 and 5 months of age and 18 months of age, respectively, administered intramuscularly into the anterolateral thigh. Subjects also received 2 oral doses of Rotarix (HRV) vaccine or placebo, at 3 and 4 months of age.	

Primary: Number of subjects reporting solicited local and general symptoms.

End point title	Number of subjects reporting solicited local and general symptoms. ^[1]
End point description:	
Assessed solicited local and general symptoms were pain, redness, swelling, drowsiness, fever [defined as axillary temperature equal to or above 37.5 degrees Celsius (°C)], irritability and loss of appetite. Any was defined as any report of the specified symptom irrespective of intensity grade and relationship to vaccination.	
End point type	Primary
End point timeframe:	
During the 4-day (Days 0-3) post-vaccination period, 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			
Subject group type	Reporting group			
Number of subjects analysed	2580			
Units: Subjects				
Any Pain, Across doses	855			
Any Redness, Across doses	907			
Any Swelling, Across doses	706			
Any Drowsiness, Across doses	929			
Any Fever (Axillary/≥ 37.5°C), Across doses	1482			
Any Irritability, Across doses	1217			
Any Loss of appetite, Across doses	1010			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any unsolicited adverse events (AEs).

End point title	Number of subjects reporting any unsolicited adverse events (AEs).
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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	Secondary
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End point timeframe:

During the 30-day follow up period (Day 0-29) after vaccination.

End point values	Infanrix- IPV+Hib Group			
Subject group type	Reporting group			
Number of subjects analysed	2590			
Units: Subjects				
Any AE(s)	914			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting large injection site swelling.

End point title	Number of subjects reporting large injection site swelling.
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End point description:

A large swelling reaction was defined as swelling with a diameter greater than (>) 50 millimeters (mm), noticeable diffuse swelling or noticeable increase of limb circumference.

End point type	Secondary
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End point timeframe:

At Month 18, post-booster dose

End point values	Infanrix- IPV+Hib Group			
Subject group type	Reporting group			
Number of subjects analysed	2540			
Units: Subjects				
Local swelling	10			
Diffuse swelling	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any serious adverse events (SAEs).

End point title	Number of subjects reporting any serious adverse events (SAEs).
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	Secondary
End point timeframe: During the entire study period.	

End point values	Infanrix-IPV+Hib Group			
Subject group type	Reporting group			
Number of subjects analysed	2590			
Units: Subjects				
Any SAE(s)	380			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited local and general adverse events (AEs): during the 4-day (Day 0–3) after vaccination.

Unsolicited local and general AEs: during the 30-day (Day 0–29) after vaccination.

Serious adverse events (SAEs): during the entire study period.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	11.0

Reporting groups

Reporting group title	Infanrix-IPV+Hib Group
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Reporting group description:

Healthy male or female subjects between and including 11 to 17 weeks of age at the time of first vaccination, who previously participated in a human rotavirus (HRV) study (444563/028), received 3 primary doses and one booster dose of Infanrix-IPV/Hib vaccine at 3,4 and 5 months of age and 18 months of age, respectively, administered intramuscularly into the anterolateral thigh. Subjects also received 2 oral doses of Rotarix (HRV) vaccine or placebo, at 3 and 4 months of age.

Serious adverse events	Infanrix-IPV+Hib Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	380 / 2590 (14.67%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Vascular disorders			
Kawasaki's disease			
alternative assessment type: Non-systematic			
subjects affected / exposed	6 / 2590 (0.23%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Haematoma			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Swelling			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Milk allergy			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Balanitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	11 / 2590 (0.42%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Bronchial hyperreactivity			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Wheezing			
alternative assessment type: Non-systematic			

subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Asthmatic crisis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Epistaxis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Interstitial lung disease			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Rhinitis allergic			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Head injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	12 / 2590 (0.46%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Foreign body trauma			
alternative assessment type: Non-systematic			

subjects affected / exposed	3 / 2590 (0.12%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Thermal burn				
alternative assessment type: Non-systematic				
subjects affected / exposed	3 / 2590 (0.12%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Arthropod bite				
alternative assessment type: Non-systematic				
subjects affected / exposed	2 / 2590 (0.08%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Skin laceration				
alternative assessment type: Non-systematic				
subjects affected / exposed	2 / 2590 (0.08%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Accidental exposure				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Burns second degree				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Overdose				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Skull fracture alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 2590 (0.04%) 0 / 1 0 / 0		
Subdural haemorrhage alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 2590 (0.04%) 0 / 1 0 / 0		
Upper limb fracture alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 2590 (0.04%) 0 / 1 0 / 0		
Congenital, familial and genetic disorders Cryptorchism alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 2590 (0.04%) 0 / 1 0 / 0		
Laryngomalacia alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 2590 (0.04%) 0 / 1 0 / 0		
Lymphangioma alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 2590 (0.04%) 0 / 1 0 / 0		
Cardiac disorders Cardiac aneurysm			

alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Febrile convulsion			
alternative assessment type: Non-systematic			
subjects affected / exposed	25 / 2590 (0.97%)		
occurrences causally related to treatment / all	0 / 25		
deaths causally related to treatment / all	0 / 0		
Convulsion			
alternative assessment type: Non-systematic			
subjects affected / exposed	7 / 2590 (0.27%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Benign intracranial hypertension			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Idiopathic thrombocytopenic purpura			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Gastritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 2590 (0.19%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 2590 (0.12%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Intussusception			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Constipation			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematemesis			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mouth ulceration				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vomiting				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Urticaria				
alternative assessment type: Non-systematic				
subjects affected / exposed	3 / 2590 (0.12%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Petechiae				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Swelling face				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urticaria chronic				
alternative assessment type: Non-systematic				

subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Vesicoureteric reflux			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchiolitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	87 / 2590 (3.36%)		
occurrences causally related to treatment / all	0 / 87		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	47 / 2590 (1.81%)		
occurrences causally related to treatment / all	0 / 47		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	45 / 2590 (1.74%)		
occurrences causally related to treatment / all	0 / 45		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	20 / 2590 (0.77%)		
occurrences causally related to treatment / all	0 / 20		
deaths causally related to treatment / all	0 / 0		
Gastritis viral			
alternative assessment type: Non-systematic			

subjects affected / exposed	16 / 2590 (0.62%)			
occurrences causally related to treatment / all	0 / 16			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	16 / 2590 (0.62%)			
occurrences causally related to treatment / all	0 / 16			
deaths causally related to treatment / all	0 / 0			
Escherichia urinary tract infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	13 / 2590 (0.50%)			
occurrences causally related to treatment / all	0 / 13			
deaths causally related to treatment / all	0 / 0			
Hand-foot-and-mouth disease				
alternative assessment type: Non-systematic				
subjects affected / exposed	13 / 2590 (0.50%)			
occurrences causally related to treatment / all	0 / 13			
deaths causally related to treatment / all	0 / 0			
Viral infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	13 / 2590 (0.50%)			
occurrences causally related to treatment / all	0 / 13			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
alternative assessment type: Non-systematic				
subjects affected / exposed	12 / 2590 (0.46%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus bronchiolitis				
alternative assessment type: Non-systematic				

subjects affected / exposed	10 / 2590 (0.39%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis rotavirus				
alternative assessment type: Non-systematic				
subjects affected / exposed	7 / 2590 (0.27%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Herpangina				
alternative assessment type: Non-systematic				
subjects affected / exposed	7 / 2590 (0.27%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
alternative assessment type: Non-systematic				
subjects affected / exposed	7 / 2590 (0.27%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Abscess limb				
alternative assessment type: Non-systematic				
subjects affected / exposed	6 / 2590 (0.23%)			
occurrences causally related to treatment / all	2 / 6			
deaths causally related to treatment / all	0 / 0			
Pharyngitis				
alternative assessment type: Non-systematic				
subjects affected / exposed	6 / 2590 (0.23%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Viral upper respiratory tract infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	6 / 2590 (0.23%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			

Gastroenteritis salmonella alternative assessment type: Non-systematic				
subjects affected / exposed	5 / 2590 (0.19%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Lobar pneumonia alternative assessment type: Non-systematic				
subjects affected / exposed	4 / 2590 (0.15%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection alternative assessment type: Non-systematic				
subjects affected / exposed	4 / 2590 (0.15%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Viral skin infection alternative assessment type: Non-systematic				
subjects affected / exposed	4 / 2590 (0.15%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Subcutaneous abscess alternative assessment type: Non-systematic				
subjects affected / exposed	3 / 2590 (0.12%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Bronchopneumonia alternative assessment type: Non-systematic				
subjects affected / exposed	2 / 2590 (0.08%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Croup infectious alternative assessment type: Non-systematic				

subjects affected / exposed	2 / 2590 (0.08%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Haematoma infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	2 / 2590 (0.08%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Otitis media				
alternative assessment type: Non-systematic				
subjects affected / exposed	2 / 2590 (0.08%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Perianal abscess				
alternative assessment type: Non-systematic				
subjects affected / exposed	2 / 2590 (0.08%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Abscess				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acarodermatitis				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Campylobacter gastroenteritis alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 2590 (0.04%) 0 / 1 0 / 0			
Cellulitis alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 2590 (0.04%) 0 / 1 0 / 0			
Conjunctivitis viral alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 2590 (0.04%) 0 / 1 0 / 0			
Dengue fever alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 2590 (0.04%) 0 / 1 0 / 0			
Epstein-barr virus infection alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 2590 (0.04%) 0 / 1 0 / 0			
Exanthema subitum alternative assessment type: Non-systematic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 2590 (0.04%) 0 / 1 0 / 0			
Folliculitis alternative assessment type: Non-systematic				

subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis bacterial				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Influenza				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Localised infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lymphadenitis bacterial				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Necrotising fasciitis				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae viral laryngotracheobronchitis				
alternative assessment type: Non-systematic				

subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Parotitis				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tonsillitis				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection bacterial				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Viral pharyngitis				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 2590 (0.04%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Decreased appetite				
alternative assessment type: Non-systematic				
subjects affected / exposed	2 / 2590 (0.08%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Failure to thrive				
alternative assessment type: Non-systematic				

subjects affected / exposed	2 / 2590 (0.08%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Dehydration			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2590 (0.04%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Infanrix-IPV+Hib Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2167 / 2590 (83.67%)		
General disorders and administration site conditions			
Pain			
subjects affected / exposed	855 / 2590 (33.01%)		
occurrences (all)	855		
Redness			
subjects affected / exposed	907 / 2590 (35.02%)		
occurrences (all)	907		
Swelling			
subjects affected / exposed	706 / 2590 (27.26%)		
occurrences (all)	706		
Drowsiness			
subjects affected / exposed	929 / 2590 (35.87%)		
occurrences (all)	929		
Fever (Axillary)			
alternative assessment type: Non-systematic			
subjects affected / exposed	1482 / 2590 (57.22%)		
occurrences (all)	1482		
Irritability			

subjects affected / exposed	1217 / 2590 (46.99%)		
occurrences (all)	1217		
Loss of appetite			
subjects affected / exposed	1010 / 2590 (39.00%)		
occurrences (all)	1010		
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	146 / 2590 (5.64%)		
occurrences (all)	146		
Infections and infestations			
Upper respiratory tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	391 / 2590 (15.10%)		
occurrences (all)	391		

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