

**Clinical trial results:**

A phase IV, open, non-randomised, multicentre study to assess the reactogenicity and immunogenicity of a booster dose of GSK Biologicals' combined reduced-antigen-content diphtheria-tetanus, acellular pertussis and inactivated poliovirus vaccine dTpa-IPV (Boostrix-Polio) when administered in healthy subjects aged 9-13 years, 5 years after previous booster vaccination with dTpa-IPV in the study 711866/001 (dTpa-IPV-001).

Summary

EudraCT number	2007-003477-94
Trial protocol	DE
Global end of trial date	08 July 2008

Results information

Result version number	v3 (current)
This version publication date	08 June 2023
First version publication date	01 May 2015
Version creation reason	

Trial information**Trial identification**

Sponsor protocol code	110947
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00635128
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)	Yes
EMA paediatric investigation plan number(s)	EMA-000500-PIP01-08
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	22 April 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 July 2008
Global end of trial reached?	Yes
Global end of trial date	08 July 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the incidence of grade 3 local reactions occurring during the 4-day (Day 0–Day 3) follow-up period after administration of a booster dose of dTpa-IPV vaccine in healthy children and adolescents aged 9 to 13 years, 5 years after a previous booster dose of the same vaccine in the study 711866/001 (dTpa-IPV-001).

Protection of trial subjects:

All subjects were supervised after vaccination/product administration 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.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 February 2008
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	Germany: 415
Worldwide total number of subjects	415
EEA total number of subjects	415

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)	0
Children (2-11 years)	415
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 (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Boostrix-Polio Group

Arm description:

Healthy male or female subjects aged 9 to 13 years, who were given a single booster dose of Boostrix-Polio vaccine in the dTPa-IPV-001 (711866/001) study, additionally received a single booster dose of the Boostrix-Polio vaccine, administered intramuscularly in the deltoid region of the non-dominant arm.

Arm type	Experimental
Investigational medicinal product name	Boostrix-Polio
Investigational medicinal product code	
Other name	dTPa-IPV vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single booster dose of the vaccine administered intramuscularly in the deltoid region of the non-dominant arm.

Arm title	Boostrix + IPV Mérieux Group
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Arm description:

Healthy male or female subjects aged 9 to 13 years, who were given a single booster dose of Boostrix-Polio vaccine in the dTPa-IPV-001 (711866/001) study, additionally received a single booster dose of the Boostrix-Polio vaccine, administered intramuscularly in the deltoid region of the non-dominant arm.

Arm type	Experimental
Investigational medicinal product name	Boostrix
Investigational medicinal product code	
Other name	dTPa vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single booster dose of the vaccine administered intramuscularly in the deltoid region of the non-dominant arm.

Investigational medicinal product name	IPV Mérieux
Investigational medicinal product code	
Other name	IPV vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single booster dose of the vaccine administered intramuscularly in the deltoid region

of the non-dominant arm.

Number of subjects in period 1	Boostrix-Polio Group	Boostrix + IPV Mérieux Group
Started	351	64
Completed	351	64

Baseline characteristics

Reporting groups

Reporting group title	Boostrix-Polio Group
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Reporting group description:

Healthy male or female subjects aged 9 to 13 years, who were given a single booster dose of Boostrix-Polio vaccine in the dTpa-IPV-001 (711866/001) study, additionally received a single booster dose of the Boostrix-Polio vaccine, administered intramuscularly in the deltoid region of the non-dominant arm.

Reporting group title	Boostrix + IPV Mérieux Group
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Reporting group description:

Healthy male or female subjects aged 9 to 13 years, who were given a single booster dose of Boostrix-Polio vaccine in the dTpa-IPV-001 (711866/001) study, additionally received a single booster dose of the Boostrix-Polio vaccine, administered intramuscularly in the deltoid region of the non-dominant arm.

Reporting group values	Boostrix-Polio Group	Boostrix + IPV Mérieux Group	Total
Number of subjects	351	64	415
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	351	64	415
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	11.4	11.3	-
standard deviation	± 0.97	± 0.72	-
Gender categorical			
Units: Subjects			
Female	169	32	201
Male	182	32	214

End points

End points reporting groups

Reporting group title	Boostrix-Polio Group
Reporting group description: Healthy male or female subjects aged 9 to 13 years, who were given a single booster dose of Boostrix-Polio vaccine in the dTpa-IPV-001 (711866/001) study, additionally received a single booster dose of the Boostrix-Polio vaccine, administered intramuscularly in the deltoid region of the non-dominant arm.	
Reporting group title	Boostrix + IPV Mérieux Group
Reporting group description: Healthy male or female subjects aged 9 to 13 years, who were given a single booster dose of Boostrix-Polio vaccine in the dTpa-IPV-001 (711866/001) study, additionally received a single booster dose of the Boostrix-Polio vaccine, administered intramuscularly in the deltoid region of the non-dominant arm.	

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

End point title	Number of subjects with any Grade 3 solicited local
End point description: Assessed solicited local symptoms were pain, redness, and swelling. Grade 3 Pain: Pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 50 millimeters (mm) of injection site. The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects for whom data were available.	
End point type	Primary
End point timeframe: During the 4-day follow-up period (Day 0-3) after booster vaccination	
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	Boostrix-Polio Group	Boostrix + IPV Mérieux Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	351	64		
Units: Subjects				
Grade 3 Pain	14	3		
Grade 3 Redness (mm)	14	5		
Grade 3 Swelling (mm)	10	5		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any solicited local symptoms

End point title	Number of subjects with any solicited local symptoms
End point description: Assessed solicited local symptoms were pain, redness, and swelling. Any = occurrence of the symptom regardless of intensity grade. The analysis was performed on the Total Vaccinated Cohort, which	

included all vaccinated subjects for whom data were available and who had the symptoms sheet filled in.

End point type	Secondary
End point timeframe:	
During the 4-day follow-up period (Day 0-3) after booster vaccination	

End point values	Boostrix-Polio Group	Boostrix + IPV Mérieux Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	351	64		
Units: Subjects				
Any Pain	257	45		
Any Redness	169	26		
Any Swelling	141	22		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any solicited general symptoms

End point title	Number of subjects with any solicited general symptoms
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End point description:

Assessed solicited general symptoms were fatigue, gastrointestinal, headache, and temperature [defined as axillary temperature equal to or above 37.5 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade and relationship to vaccination. The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects for whom data were available and who had the symptoms sheet filled in.

End point type	Secondary
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End point timeframe:

During the 4-day (Day 0–3) follow-up period after booster vaccination

End point values	Boostrix-Polio Group	Boostrix + IPV Mérieux Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	351	63		
Units: Subjects				
Any Fatigue	87	14		
Any Gastrointestinal	41	4		
Any Headache	76	12		
Any Temperature	14	0		

Statistical analyses

Secondary: Number of subjects with anti-diphtheria (Anti-D) and anti-tetanus (Anti-T) toxoids

End point title	Number of subjects with anti-diphtheria (Anti-D) and anti-tetanus (Anti-T) toxoids
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End point description:

Anti-D and anti-T antibody concentration greater than or equal to (\geq) 0.1 international units per milliliter (IU/mL) and ≥ 1 IU/mL have been assessed by enzyme-linked immunosorbent assay (ELISA). Pre-vaccination sera with ELISA concentrations < 0.1 IU/mL were tested for neutralising antibodies using a Vero-cell neutralisation assay with a 0.016 IU/mL cut-off. The analysis was performed on the According-to-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects vaccinated with a booster dose of Boostrix-Polio vaccine in this current study (110947), for whom immunogenicity data and assay results for antibodies against at least one study vaccine antigen component were available.

End point type	Secondary
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End point timeframe:

Prior to (Month 0) and one month after (Month 1) booster vaccination

End point values	Boostrix-Polio Group	Boostrix + IPV Mérieux Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	336	62		
Units: Subjects				
Anti-D ≥ 0.1 IU/mL, M0 (N=334,62)	298	53		
Anti-D ≥ 0.1 IU/mL, M1 (N=336,62)	336	62		
Anti-D ≥ 1 IU/mL, M0 (N=334,62)	91	13		
Anti-D ≥ 1 IU/mL, M1 (N=336,62)	308	55		
Anti-T ≥ 0.1 IU/mL, M0 (N=335,62)	330	61		
Anti-T ≥ 0.1 IU/mL, M1 (N=336,62)	336	62		
Anti-T ≥ 1 IU/mL, M0 (N=335,62)	181	35		
Anti-T ≥ 1 IU/mL, M1 (N=336,62)	335	61		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-D and anti-T antibody concentrations

End point title	Anti-D and anti-T antibody concentrations
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End point description:

Antibody concentrations were presented as geometric mean concentrations (GMCs), expressed in international units per milliliter (IU/mL). The analysis was performed on the According-to-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects vaccinated with a booster dose of Boostrix-Polio vaccine in this current study (110947), for whom immunogenicity data and assay results for antibodies against at least one study vaccine antigen component were available.

End point type	Secondary
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End point timeframe:

Prior to (Month 0) and one month after (Month 1) booster vaccination

End point values	Boostrix-Polio Group	Boostrix + IPV Mérimex Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	336	62		
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D, M0 (N=334,62)	0.51 (0.429 to 0.608)	0.446 (0.305 to 0.651)		
Anti-D, M1 (N=336,62)	4.784 (4.302 to 5.32)	4.153 (3.089 to 5.585)		
Anti-T, M0 (N=335,62)	1.197 (1.045 to 1.37)	1.067 (0.797 to 1.429)		
Anti-T, M1 (N=336,62)	11.81 (11.011 to 12.667)	9.518 (7.879 to 11.498)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects for anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN)

End point title	Number of seropositive subjects for anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN)
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End point description:

A seropositive subject was defined as a subject with anti-PT, anti-FHA, and anti-PRN antibody concentrations ≥ 5 ELISA units per milliliter (EL.U/ml). The analysis was performed on the According-to-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects vaccinated with a booster dose of Boostrix-Polio vaccine in this current study (110947), for whom immunogenicity data and assay results for antibodies against at least one study vaccine antigen component were available.

End point type	Secondary
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End point timeframe:

Prior to (Month 0) and one month after (Month 1) booster vaccination

End point values	Boostrix-Polio Group	Boostrix + IPV Mérimex Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	336	62		
Units: Subjects				
Anti-PT, M0 (N=330,62)	134	21		
Anti-PT, M1 (N=335,62)	334	59		
Anti-FHA, M0 (N=333,60)	332	60		
Anti-FHA, M1 (N=336,61)	336	61		
Anti-PRN, M0 (N=335,62)	325	57		
Anti-PRN, M1 (N=336,62)	336	62		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN) antibody concentrations

End point title	Anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN) antibody concentrations
End point description: Antibodies concentrations were presented as geometric mean concentrations (GMCs), expressed in EL.U/mL.	
End point type	Secondary
End point timeframe: Prior to (Month 0) and one month after (Month 1) booster vaccination	

End point values	Boostrix-Polio Group	Boostrix + IPV Mérieux Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	336	62		
Units: EL.U/ml				
geometric mean (confidence interval 95%)				
Anti-PT, M0 (N=330,62)	5.2 (4.7 to 5.9)	4.5 (3.6 to 5.6)		
Anti-PT, M1 (N=335,62)	41.6 (38.1 to 45.3)	32 (24.5 to 41.9)		
Anti-FHA, M0 (N=333,60)	69.8 (62.1 to 78.4)	70.1 (52.5 to 93.5)		
Anti-FHA, M1 (N=336,61)	662.7 (613.2 to 716.1)	733.9 (733.9 to 882.5)		
Anti-PRN, M0 (N=335,62)	46.8 (41.5 to 52.8)	41.1 (30 to 56.2)		
Anti-PRN, M1 (N=336,62)	570.8 (527.4 to 617.7)	460.4 (353.3 to 600)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-polio type 1, 2 and 3 antibody titers ≥ 8

End point title	Number of subjects with anti-polio type 1, 2 and 3 antibody titers ≥ 8
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End point description:

Antibody titers were presented as geometric mean titers (GMTs). The analysis was performed on the According-to-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects vaccinated with a booster dose of Boostrix-Polio vaccine in this current study (110947), for whom immunogenicity data and assay results for antibodies against at least one study vaccine antigen component were available.

End point type	Secondary
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End point timeframe:

Prior to (Month 0) and one month after (Month 1) booster vaccination

End point values	Boostrix-Polio Group	Boostrix + IPV Mérieux Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	335	62		
Units: Subjects				
Anti-polio 1, Pre [N=333;62]	329	60		
Anti-polio 1, Post [N=335;62]	335	62		
Anti-polio 2, Pre [N=334;62]	333	62		
Anti-polio 2, Post [N=335;62]	335	62		
Anti-polio 3, Pre [N=334;62]	324	60		
Anti-polio 3, Post [N=333;62]	333	62		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polio type 1, 2 and 3 (Anti-Polio 1, 2 and 3) antibody titers

End point title	Anti-polio type 1, 2 and 3 (Anti-Polio 1, 2 and 3) antibody titers
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End point description:

Antibody titers were presented as geometric mean titers (GMTs). The analysis was performed on the According-to-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects vaccinated with a booster dose of Boostrix-Polio vaccine in this current study (110947), for whom immunogenicity data and assay results for antibodies against at least one study vaccine antigen component were available.

End point type	Secondary
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End point timeframe:

Prior to (Month 0) and one month after (Month 1) booster vaccination

End point values	Boostrix-Polio Group	Boostrix + IPV Mérieux Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	335	62		
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-polio 1, M0 (N=333,62)	138.7 (123 to 156.4)	128.9 (96.1 to 172.7)		

Anti-polio 1, M1 (N=335,62)	1359.6 (1213.4 to 1523.3)	1088.9 (866.5 to 1368.4)		
Anti-polio 2, M0 (N=334,62)	166.3 (149.5 to 185)	179.2 (142.9 to 224.7)		
Anti-polio 2, M1 (N=335,62)	1629.4 (1475.2 to 1799.7)	1309.5 (1035.2 to 1656.3)		
Anti-polio 3, M0 (N=334,62)	117.2 (102.8 to 133.5)	118.4 (83.4 to 168)		
Anti-polio 3, M1 (N=333,62)	1882.4 (1687.9 to 2099.3)	1712.5 (1329.2 to 2206.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with booster response to anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN)

End point title	Number of subjects with booster response to anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN)
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End point description:

Booster vaccine response was defined as the appearance of antibodies in subjects who were seronegative at the pre-vaccination time point (i.e. with concentrations lesser than(<) 5 EL.U/mL) or at least a 2-fold increase of pre-vaccination antibody concentrations in subjects who were seropositive at the pre-vaccination time point (i.e. with concentrations < 5 EL.U/mL). The analysis was performed on the According-to-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects vaccinated with a booster dose of Boostrix-Polio vaccine in this current study (110947), for whom immunogenicity data and assay results for antibodies against at least one study vaccine antigen component were available.

End point type	Secondary
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End point timeframe:

One month after booster vaccination (At Month 1)

End point values	Boostrix-Polio Group	Boostrix + IPV Mérieux Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	335	62		
Units: Subjects				
Anti-PT [N=330;62]	308	56		
Anti-FHA [N=333;60]	311	56		
Anti-PRN [N=335;62]	319	61		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited adverse events (AEs)

End point title	Number of subjects with unsolicited adverse events (AEs)
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End point description:

AEs results are presented for all subjects. 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. The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects for whom data were available

End point type	Secondary
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End point timeframe:

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

End point values	Boostrix-Polio Group	Boostrix + IPV Mérieux Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	351	64		
Units: Subjects	47	17		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events (SAEs)

End point title	Number of subjects with serious adverse events (SAEs)
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End point description:

SAEs results are presented for all subjects. Assessed SAEs include medical occurrences that result in death, are life-threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity. The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects for whom data were available.

End point type	Secondary
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End point timeframe:

During the entire booster period (Month 0 to Month 1)

End point values	Boostrix-Polio Group	Boostrix + IPV Mérieux Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	351	64		
Units: Subjects	0	0		

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited local/general symptoms during the 4-day (Days 0-3) post-booster period; AEs during the 31-day (Days 0-30) post-booster period; SAEs following booster vaccination (up to Month 1).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	11.0
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Reporting groups

Reporting group title	Boostrix-Polio Group
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Reporting group description:

Healthy male or female subjects aged 9 to 13 years, who were given a single booster dose of Boostrix-Polio vaccine in the dTpa-IPV-001 (711866/001) study, additionally received a single booster dose of the Boostrix-Polio vaccine, administered intramuscularly in the deltoid region of the non-dominant arm.

Reporting group title	Boostrix + IPV Mérieux Group
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Reporting group description:

Healthy male or female subjects aged 9 to 13 years, who were given a single booster dose of Boostrix and IPV Mérieux® vaccines in the dTpa-IPV-001 (711866/001) study, additionally received a single booster dose of the Boostrix-Polio vaccine, administered intramuscularly in the deltoid region of the non-dominant arm.

Serious adverse events	Boostrix-Polio Group	Boostrix + IPV Mérieux Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 351 (0.00%)	0 / 64 (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	Boostrix-Polio Group	Boostrix + IPV Mérieux Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	281 / 351 (80.06%)	51 / 64 (79.69%)	
General disorders and administration site conditions			
Pain			
subjects affected / exposed	257 / 351 (73.22%)	45 / 64 (70.31%)	
occurrences (all)	0	0	
Redness			

subjects affected / exposed	169 / 351 (48.15%)	26 / 64 (40.63%)	
occurrences (all)	0	0	
Swelling			
subjects affected / exposed	141 / 351 (40.17%)	22 / 64 (34.38%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed ^[1]	87 / 351 (24.79%)	14 / 63 (22.22%)	
occurrences (all)	0	0	
Gastrointestinal			
subjects affected / exposed ^[2]	41 / 351 (11.68%)	3 / 63 (4.76%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed ^[3]	76 / 351 (21.65%)	12 / 63 (19.05%)	
occurrences (all)	0	0	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

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