Clinical trial results:
A phase III, open-label, randomised multicentre study to evaluate the immunogenicity and safety of a booster dose of GlaxoSmithKline Biologicals' dTpa-IPV vaccine (Boostrix Polio) compared with Sanofi Pasteur MSD's dTpa-IPV vaccine (Repevax), when co-administered with GSK Biologicals' MMR vaccine (Priorix) in 3 and 4-year-old healthy children.

Summary

EudraCT number	2009-012202-39
Trial protocol	GB
Global end of trial date	

Results information

Result version number	v2
This version publication date	08 July 2016
First version publication date	06 June 2015
Version creation reason	• New data added to full data set Data for secondary endpoints have been added.

Trial information

Trial identification

Sponsor protocol code	111763

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01245049
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, 0044 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 0044 2089904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-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	Interim
Date of interim/final analysis	27 March 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 March 2012
Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

• To demonstrate that GSK Biologicals' dTpa-IPV vaccine is non-inferior to Sanofi Pasteur MSD's dTpa-IPV vaccine in terms of percentages of subjects with immune response to the diphtheria, tetanus and polio antigens, one month after booster vaccination.

• To demonstrate that GSK Biologicals' dTpa-IPV vaccine given as a single booster dose in this study is non-inferior to GSK Biologicals' DTPa vaccine (Infanrix) given as a primary series in the German household contact study APV-039 in terms of anti-PT, anti-FHA and anti-PRN geometric mean concentrations (GMCs), one month after booster vaccination.

Protection of trial subjects:

The vaccine was administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may have occurred following an intramuscular administration to these subjects. Firm pressure was applied to the injection site (without rubbing) for at least two minutes.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 April 2011
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	United Kingdom: 385
Worldwide total number of subjects	385
EEA total number of subjects	385

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)	385

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 trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Boostrix Polio Group

Arm description:

Subjects received 1 booster dose of Boostrix Polio vaccine co-administered with Priorix.

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

Dosage and administration details:

1 dose of Boostrix™ Polio co-administered with Priorix™.

Investigational medicinal product name	Priorix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose of Boostrix™ Polio co-administered with Priorix™.

Arm title	Repevax Group

Arm description:

Subjects received 1 booster dose of Repevax vaccine co-administered with Priorix vaccine.

Arm type	Active comparator
Investigational medicinal product name	Repevax™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose of Repevax™ Polio co-administered with Priorix™.

Investigational medicinal product name	Priorix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose of Repevax™ co-administered with Priorix™.

Number of subjects in period 1	Boostrix Polio Group	Repevax Group
Started	255	130
Completed	254	126
Not completed	1	4
Consent withdrawn by subject	-	1
Lost to follow-up	-	2
Migrated/moved from study area	-	1
Lost to follow-up	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Boostrix Polio Group
Reporting group description:	
Subjects received 1 booster dose of Boostrix Polio vaccine co-administered with Priorix.	
Reporting group title	Repevax Group
Reporting group description:	
Subjects received 1 booster dose of Repevax vaccine co-administered with Priorix vaccine.	

Reporting group values	Boostrix Polio Group	Repevax Group	Total
Number of subjects	255	130	385
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: years			
arithmetic mean	3.1	3.1	
standard deviation	± 0.2	± 0.2	-
Gender categorical Units: Subjects			
Female	123	65	188
Male	132	65	197

End points

End points reporting groups

Reporting group title	Boostrix Polio Group
Reporting group description:	
Subjects received 1 booster dose of Boostrix Polio vaccine co-administered with Priorix.	
Reporting group title	Repevax Group
Reporting group description:	
Subjects received 1 booster dose of Repevax vaccine co-administered with Priorix vaccine.	

Primary: Number of subjects with a booster response to diphtheria (D) and tetanus (T) antibodies

End point title	Number of subjects with a booster response to diphtheria (D) and tetanus (T) antibodies
End point description:	
Booster response was defined as: For initially seronegative subjects, antibody concentrations at least four times the assay cut-off; For initially seropositive subjects, an increase in antibody concentrations of at least four times the Pre booster vaccination concentration.	
End point type	Primary
End point timeframe:	
One month after booster vaccination	

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	90		
Units: Subject				
Anti-D [N=177;90]	176	90		
Anti-T [N=176;90]	173	90		

Statistical analyses

Statistical analysis title	Non-inferiority in terms of booster response to D
Comparison groups	Boostrix Polio Group v Repevax Group
Number of subjects included in analysis	267
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Method	Standardized asymptotic
Parameter estimate	Percentage difference
Point estimate	0.56

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.55
upper limit	3.14

Notes:

[1] - To assess the Non-inferiority of the Boostrix Polio Group compared to the Repevax Group in terms of booster response to diphtheria, standardized asymptotic 95% CI for the groups'difference [Repevax Group minus Boostrix Polio Group] was computed.

Non-inferiority criterion: Upper limit of the 95% CI of the groups' difference in booster response rate ≤10%.

Statistical analysis title	Non-inferiority in terms of booster response to T
Comparison groups	Boostrix Polio Group v Repevax Group
Number of subjects included in analysis	267
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Parameter estimate	Percentage difference
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.43
upper limit	4.9

Notes:

[2] - To assess the Non-inferiority of the Boostrix Polio Group compared to the Repevax Group in terms of booster response to tetanus, standardized asymptotic 95% CI for the groups' difference [Repevax Group minus Boostrix Polio Group] was computed.

Non-inferiority criterion: Upper limit of the 95% CI of the groups' difference in booster response rate ≤10%

Primary: Concentrations for anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN)

End point title	Concentrations for anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN)[3]

End point description:

End point type	Primary

End point timeframe:

Before (PRE) and one month after (POST) the booster vaccination

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 primary end point was descriptive, no statistical hypothesis test was performed.

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	195	96		
Units: EU/mL				
geometric mean (confidence interval 95%)				

Anti-PT PRE [N=171;90]	3.4 (3 to 3.9)	3.2 (2.9 to 3.6)		
Anti-PT POST [N=194;96]	70.1 (62.2 to 79)	47.8 (39.9 to 57.3)		
Anti-FHA PRE [N=174;85]	12.9 (10 to 16.6)	10.7 (7.9 to 14.5)		
Anti-FHA POST [N=195;95]	358.3 (312.5 to 410.8)	164.8 (138.5 to 196.1)		
Anti-PRN PRE [N=175;91]	4.3 (3.8 to 5)	4.3 (3.7 to 5)		
Anti-PRN POST [N=195;94]	151.4 (127.5 to 179.6)	209.8 (168.5 to 261.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Anti-Polio type 1, 2 and 3 antibody titers

End point title	Anti-Polio type 1, 2 and 3 antibody titers

End point description:

Results for the one month after (POST) booster vaccination timepoint were the primary outcome.

End point type	Primary

End point timeframe:

Prior to (PRE) and one month after (POST) booster vaccination

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	160	81		
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-Polio 1, PRE (N=160;77)	12.8 (10.6 to 15.5)	13.2 (10.2 to 17.1)		
Anti-Polio 1, POST (N=157,75)	2183.3 (1812.4 to 2630.1)	1876.1 (1472.8 to 2389.7)		
Anti-Polio 2, PRE (N=159;79)	15.5 (12.8 to 18.8)	14.6 (11.3 to 18.8)		
Anti-Polio 2, POST (N=124,71)	2693.1 (2176.3 to 3332.5)	2203.8 (1681 to 2889.4)		
Anti-Polio 3, PRE (N=156;79)	15.4 (12.7 to 18.8)	14.5 (10.4 to 20.1)		
Anti-Polio 3, POST (N=159,81)	3762.4 (3080.9 to 4594.6)	4185.1 (3318.3 to 5278.3)		

Statistical analyses

Statistical analysis title	Immune response difference to anti-Polio 1 antigen
Comparison groups	Boostrix Polio Group v Repevax Group
Number of subjects included in analysis	241
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Method	ANCOVA
Parameter estimate	Difference in adjusted GMT ratio
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.28

Notes:

[4] - Non-inferiority in terms of response to the poliovirus types 1, 2 and 3 was demonstrated if the upper limit of the 95% confidence interval (CI) on the ratio of geometric mean titres (GMTs) [Repevax Group divided by Boostrix-Polio Group] was ≤ 2.

Statistical analysis title	Immune response difference to anti-Polio 2 antigen
Comparison groups	Boostrix Polio Group v Repevax Group
Number of subjects included in analysis	241
Analysis specification	Pre-specified
Analysis type	non-inferiority[5]
Method	ANCOVA
Parameter estimate	Difference in adjusted GMT ratio
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.12

Notes:

[5] - Non-inferiority in terms of response to the poliovirus types 1, 2 and 3 was demonstrated if the upper limit of the 95% confidence interval (CI) on the ratio of geometric mean titres (GMTs) [Repevax Group divided by Boostrix-Polio Group] was ≤ 2.

Statistical analysis title	Immune response difference to anti-Polio 3 antigen
Comparison groups	Boostrix Polio Group v Repevax Group
Number of subjects included in analysis	241
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
Method	ANCOVA
Parameter estimate	Difference in adjusted GMT ratio
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.84

Notes:

[6] - Non-inferiority in terms of response to the poliovirus types 1, 2 and 3 was demonstrated if the upper limit of the 95% confidence interval (CI) on the ratio of geometric mean titres (GMTs) [Repevax Group divided by Boostrix-Polio Group] was ≤ 2.

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)

End point description:

A seropositive subject for anti-PT, anti-FHA and anti-PRN was a subject whose antibody concentration was ≥ 5 EL.U/mL.

End point type	Secondary

End point timeframe:

Before (PRE) and one month after (POST) the booster vaccination

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	195	96		
Units: Subject				
Anti-PT PRE [N=171;90]	31	18		
Anti-PT POST [N=194;96]	194	96		
Anti-FHA PRE [N=174;85]	112	60		
Anti-FHA POST [N=195;95]	195	95		
Anti-PRN PRE [N=175;91]	61	37		
Anti-PRN POST [N=195;94]	194	94		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects for anti-D and anti-T

End point title	Number of seroprotected subjects for anti-D and anti-T

End point description:

A seroprotected subject was defined a subject with antibody concentrations ≥ 0.1 international units per millilitre (IU/mL).

End point type	Secondary

End point timeframe:

Before (PRE) and one month after (POST) the booster vaccination.

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	195	96		
Units: Subject				
Anti-D PRE [N=177;90]	136	75		
Anti-D POST [N=195;96]	195	96		
Anti-T PRE [N=177;90]	116	63		

Anti-T POST [N=194;96]	194	96		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-D and anti-T

End point title	Concentrations for anti-D and anti-T

End point description:

End point type	Secondary

End point timeframe:

Before (PRE) and one month after (POST) the booster vaccination.

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	195	96		
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D PRE [N=177;90]	0.228 (0.194 to 0.267)	0.259 (0.209 to 0.32)		
Anti-D POST [N=195;96]	8.113 (7.259 to 9.068)	11.948 (10.003 to 14.271)		
Anti-T PRE [N=177;90]	0.209 (0.173 to 0.253)	0.241 (0.184 to 0.315)		
Anti-T POST [N=194;96]	6.787 (5.961 to 7.727)	9.194 (7.565 to 11.175)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroconverted subjects for anti-measles

End point title	Number of seroconverted subjects for anti-measles

End point description:

A converted subject was defined an initially seronegative subject with antibody concentrations ≥ 150 milli-international units per millilitre (mIU/mL).

End point type	Secondary

End point timeframe:

Before (PRE) and one month after (POST) the booster vaccination

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	2		
Units: Subject				
Anti-measles PRE [N=4;2]	0	0		
Anti-measles POST [N=4;2]	4	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroconverted subjects for anti-mumps

End point title	Number of seroconverted subjects for anti-mumps

End point description:

A converted subject was defined an initially seronegative subject with antibody concentrations ≥ 231 units per millilitre (U/mL).

End point type	Secondary

End point timeframe:

Before (PRE) and one month after (POST) the booster vaccination

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	7		
Units: Subjects				
Anti-mumps PRE [N=16;7]	0	0		
Anti-mumps POST [N=11;6]	11	6		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with a booster response to PT, FHA and PRN antibodies

End point title	Number of subjects with a booster response to PT, FHA and PRN antibodies

End point description:

Booster response was defined as:
For initially seronegative subjects, antibody concentrations at least four times the assay cut-off;
For initially seropositive subjects, an increase in antibody concentrations of at least four times the Pre booster vaccination concentration.

End point type	Secondary

End point timeframe:

One month after the booster vaccination

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	175	90		
Units: Subjects				
Anti-PT [N=170;90]	154	73		
Anti-FHA [N=174;85]	165	79		
Anti-PRN [N= 175;89]	169	89		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited local symptoms

End point title	Number of subjects with solicited local symptoms

End point description:

End point type	Secondary

End point timeframe:

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

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	255	125		
Units: Subjects				
Any Pain (N=255;125)	127	70		
Any Redness (N=255;125)	146	73		
Any Swelling (N=255;125)	92	53		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited general symptoms

End point title	Number of subjects with solicited general symptoms

End point description:

End point type	Secondary

End point timeframe:

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

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	255	125		
Units: Subjects				
Drowsiness [N=255;125]	77	39		
Irritability [N=255;125]	107	49		
Loss of appetite [N=255;125]	67	30		
Temperature [N=255;125]	18	9		

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)

End point description:

End point type	Secondary

End point timeframe:

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

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	255	130		
Units: Subjects				
AEs [N=255;130]	88	36		

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)

End point description:

End point type	Secondary

End point timeframe:
During the entire study period

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	225	130		
Units: Subjects				
SAEs [N=255;130]	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-measles antibody concentrations ≥ 150 milli-international units per millilitre (mIU/mL)

End point title	Number of subjects with anti-measles antibody concentrations ≥ 150 milli-international units per millilitre (mIU/mL)

End point description:

End point type	Secondary

End point timeframe:
Prior to (PRE) and one month after (POST) booster vaccination

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	76		
Units: Subjects				
Anti-Measles, PRE (N=159;76)	155	74		
Anti-Measles, POST (N=136;68)	136	68		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-mumps antibody concentrations ≥ 231 units per millilitre (U/mL)

End point title	Number of subjects with anti-mumps antibody concentrations ≥ 231 units per millilitre (U/mL)

End point description:

End point type	Secondary

End point timeframe:
Prior to (PRE) and one month after (POST) booster vaccination

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	156	76		
Units: Subjects				
Anti-Mumps, PRE (N=156;76)	140	69		
Anti-Mumps, POST (N=133;68)	133	68		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-rubella antibody concentrations ≥ 4 international units per millilitre (IU/mL)

End point title	Number of subjects with anti-rubella antibody concentrations ≥ 4 international units per millilitre (IU/mL)

End point description:

End point type	Secondary

End point timeframe:
Prior to (PRE) and one month after (POST) booster vaccination

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	158	76		
Units: Subjects				
Anti-Rubella, PRE (N=158;76)	158	76		
Anti-Rubella, POST (N=134;68)	134	68		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-Mumps antibody concentrations

End point title	Anti-Mumps antibody concentrations

End point description:

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month after (POST) booster vaccination

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	156	76		
Units: U/mL				
geometric mean (confidence interval 95%)				
Anti-Mumps, PRE (N=156;76)	1035.3 (869.8 to 1232.3)	971.7 (752.1 to 1255.5)		
Anti-Mumps, POST (N=133;68)	6801.9 (6155 to 7516.8)	6219.4 (5365.8 to 7208.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-measles antibody concentrations

End point title	Anti-measles antibody concentrations

End point description:

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month after (POST) booster vaccination

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	76		
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-Measles, PRE (N=159;76)	2644 (2261.3 to 3091.6)	2702.6 (2146 to 3403.6)		
Anti-Measles, POST (N=136;68)	3817.7 (3422.3 to 4258.8)	3798 (3262.6 to 4421.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-rubella antibody concentrations

End point title	Anti-rubella antibody concentrations

End point description:

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month after (POST) booster vaccination

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	158	76		
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-Rubella, PRE (N=158;76)	66.5 (59.1 to 74.8)	72.6 (59.8 to 88.1)		
Anti-Rubella, POST (N=134;68)	134.3 (120.7 to 149.4)	130.3 (111.7 to 152)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with booster response for anti- Polio 1, 2 and 3 antigens

End point title	Number of subjects with booster response for anti- Polio 1, 2 and 3 antigens

End point description:

Booster response defined as:
For initially seronegative subjects, antibody titers at least four times the cut-off (post-vaccination titer ≥ 32);
For initially seropositive subjects, an increase in antibody titers of at least four times the Pre booster vaccination titer.

End point type	Secondary

End point timeframe:

At one month after (POST) booster vaccination

End point values	Boostrix Polio Group	Repevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	131	68		
Units: Subjects				
Anti-Polio 1 (N=131;63)	129	63		
Anti-Polio 2 (N=100;61)	99	59		
Anti-Polio 3 (N=126;68)	124	68		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

- Solicited local and general symptoms: during the 4 day- (Day 0-Day 3) after vaccination;
- Unsolicited adverse events: during the 31 day (Day 0-Day 30) after vaccination;
- Serious adverse event from the booster dose up to study end.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups

Reporting group title	Repevax Group

Reporting group description:

Subjects received 1 booster dose of Repevax vaccine co-administered with Priorix vaccine.

Reporting group title	Boostrix Polio Group

Reporting group description:

Subjects received 1 booster dose of Boostrix Polio vaccine co-administered with Priorix.

Serious adverse events	Repevax Group	Boostrix Polio Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 130 (0.00%)	1 / 255 (0.39%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Respiratory, thoracic and mediastinal disorders			
Pneumonia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 130 (0.00%)	1 / 255 (0.39%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Repevax Group	Boostrix Polio Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	73 / 130 (56.15%)	146 / 255 (57.25%)	
General disorders and administration site conditions			
Pain			

subjects affected / exposed[1]	70 / 125 (56.00%)	127 / 255 (49.80%)	
occurrences (all)	70	127	
Redness			
subjects affected / exposed[2]	73 / 125 (58.40%)	146 / 255 (57.25%)	
occurrences (all)	73	146	
Swelling			
alternative assessment type: Non-systematic			
subjects affected / exposed[3]	53 / 125 (42.40%)	92 / 255 (36.08%)	
occurrences (all)	53	92	
Drowsiness			
subjects affected / exposed[4]	39 / 125 (31.20%)	77 / 255 (30.20%)	
occurrences (all)	39	77	
Irritability			
subjects affected / exposed[5]	49 / 125 (39.20%)	107 / 255 (41.96%)	
occurrences (all)	49	107	
Loss of appetite			
subjects affected / exposed[6]	30 / 125 (24.00%)	67 / 255 (26.27%)	
occurrences (all)	30	67	
Temperature/(Axillary)			
subjects affected / exposed[7]	9 / 125 (7.20%)	18 / 255 (7.06%)	
occurrences (all)	9	18	

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.

[4] - 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.

[5] - 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.

[6] - 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.

[7] - 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