Clinical trial results:
Immunogenicity and Safety of the Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) Administered at 2, 3, and 4 Months of Age and Followed by a Booster Dose at 18 Months of age in Healthy Infants in China, versus Commercially Available Oral Poliomyelitis Vaccine

Summary

EudraCT number	2015-005182-23
Trial protocol	Outside EU/EEA
Global end of trial date	03 March 2008

Results information

Result version number	v1 (current)
This version publication date	16 April 2016
First version publication date	16 April 2016

Trial information

Trial identification

Sponsor protocol code	IPV13

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00348387
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur China
Sponsor organisation address	6th floor, No. 112 Jian Guo Lu, Chaoyang District, Beijing, China, 100022
Public contact	Local Medical Director, Sanofi Pasteur China, 86 10 6568 5588, Reinel.Zhang@sanofipasteur.com
Scientific contact	Local Medical Director, Sanofi Pasteur China, 86 10 6568 5588, Reinel.Zhang@sanofipasteur.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?	Yes
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 November 2008
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 March 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To demonstrate the non-inferiority in terms of seroprotection rates (polio types 1, 2 and 3) of IMOVAX Polio™ versus commercially available OPV one month after the 3-dose primary vaccination.

Protection of trial subjects:

Only subjects that met all the study inclusion and none of the exclusion criteria were randomized and vaccinated in the study. Vaccinations were performed by qualified and trained study personnel. Subjects with allergy to any of the vaccine components were not vaccinated. After vaccination, subjects were also kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment was also available on site in case of any immediate allergic reactions.

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	21 June 2006
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	China: 600
Worldwide total number of subjects	600
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)	600
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:

Study subjects were enrolled from 21 June 2006 to 27 September 2006 at 1 clinic center in China.

Pre-assignment

Screening details:

A total of 600 infants met all of the inclusion and none of the exclusion criteria were enrolled and vaccinated in the primary vaccination phase of this study; 267 infants in the IPV group received the booster vaccination.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Not applicable

Arms

Are arms mutually exclusive?	Yes
Arm title	IMOVAX Polio™ Group

Arm description:

Infants received the IMOVAX Polio™ (IPV) vaccine at 2, 3, and 4 months of age and a booster dose of IPV vaccine 14-16 months after the three-dose primary vaccination.

Arm type	Experimental
Investigational medicinal product name	IPV vaccine (IMOVAX Polio™)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL, intramuscular into the anterolateral area of the right thigh, 1 injection each at 2, 3, and 4 months of age.

Arm title	Oral Poliomyelitis Vaccine Group

Arm description:

Infants received the commercially available Oral Poliomyelitis Vaccine (OPV) vaccine at 2, 3, and 4 months of age.

Arm type	Active comparator
Investigational medicinal product name	Poliomyelitis Vaccine in Dragee Candy (Human Diploid Cell), Live OPV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

1 g dragee, oral, 1 administration each at 2, 3, and 4 months of age.

Number of subjects in period 1	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group
Started	300	300
Completed	264	282
Not completed	36	18
Consent withdrawn by subject	29	14
Adverse event, non-fatal	1	1
Serious adverse event	1	-
Lost to follow-up	4	3
Protocol deviation	1	-

Baseline characteristics

Reporting groups	
Reporting group title	IMOVAX Polio™ Group
Reporting group description:	
Infants received the IMOVAX Polio™ (IPV) vaccine at 2, 3, and 4 months of age and a booster dose of IPV vaccine 14-16 months after the three-dose primary vaccination.	
Reporting group title	Oral Poliomyelitis Vaccine Group
Reporting group description:	
Infants received the commercially available Oral Poliomyelitis Vaccine (OPV) vaccine at 2, 3, and 4 months of age.	

Reporting group values	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group	Total
Number of subjects	300	300	600
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)	300	300	600
Children (2-11 years)	0	0	0
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: days			
arithmetic mean	64.7	64.9	
standard deviation	± 3	± 2.9	-
Gender categorical Units: Subjects			
Female	132	128	260
Male	168	172	340

End points

End points reporting groups

Reporting group title	IMOVAX Polio™ Group
Reporting group description:	
Infants received the IMOVAX Polio™ (IPV) vaccine at 2, 3, and 4 months of age and a booster dose of IPV vaccine 14-16 months after the three-dose primary vaccination.	
Reporting group title	Oral Poliomyelitis Vaccine Group
Reporting group description:	
Infants received the commercially available Oral Poliomyelitis Vaccine (OPV) vaccine at 2, 3, and 4 months of age.	

Primary: Percentage of Infant Subjects with Seroprotection Against Poliovirus 1, 2 and 3 Following A Three-Dose Primary Vaccination series with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis Vaccine

End point title	Percentage of Infant Subjects with Seroprotection Against Poliovirus 1, 2 and 3 Following A Three-Dose Primary Vaccination series with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis Vaccine
End point description:	
Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure. Seroprotection was defined as Anti-Poliovirus type 1, 2, and 3 antibody titers ≥ 8 (1/dil).	
End point type	Primary
End point timeframe:	
1 month post-dose 3 primary vaccination	

End point values	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	186	193		
Units: Percentage of subjects				
number (not applicable)				
Anti-Poliovirus 1	100	97.41		
Anti-Poliovirus 2	97.31	100		
Anti-Poliovirus 3	98.92	95.34		

Statistical analyses

Statistical analysis title	Non-inferiority; Anti-Poliovirus 1
Statistical analysis description:	
This was a non-inferiority analysis of IMOVAX Polio™ compared to OPV for Anti-Poliovirus type 1.	
Comparison groups	IMOVAX Polio™ Group v Oral Poliomyelitis Vaccine Group

Number of subjects included in analysis	379
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Parameter estimate	IPV-OPV
Point estimate	2.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.08
upper limit	5.92

Notes:

[1] - Non-inferiority was established if the lower limit of the two-sided 95% CI for seroprotection rate was greater than -10%. IMOVAX Polio™ was non-inferior to OPV for Anti-Poliovirus type 1.

Statistical analysis title	Non-inferiority; Anti-Poliovirus 2

Statistical analysis description:

This was a non-inferiority analysis of IMOVAX Polio™ compared to OPV for Anti-Poliovirus type 2.

Comparison groups	IMOVAX Polio™ Group v Oral Poliomyelitis Vaccine Group
Number of subjects included in analysis	379
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Parameter estimate	IPV-OPV
Point estimate	-2.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.14
upper limit	-0.21

Notes:

[2] - Non-inferiority was established if the lower limit of the two-sided 95% CI for seroprotection rate was greater than -10%. IMOVAX Polio™ was non-inferior to OPV for Anti-Poliovirus type 2.

Statistical analysis title	Non-inferiority; Anti-Poliovirus 3

Statistical analysis description:

This was a non-inferiority analysis of IMOVAX Polio™ compared to OPV for Anti-Poliovirus type 3.

Comparison groups	IMOVAX Polio™ Group v Oral Poliomyelitis Vaccine Group
Number of subjects included in analysis	379
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	IPV-OPV
Point estimate	3.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	7.62

Notes:

[3] - Non-inferiority was established if the lower limit of the two-sided 95% CI for seroprotection rate was greater than -10%. IMOVAX Polio™ was non-inferior to OPV for Anti-Poliovirus type 3.

Secondary: Geometric Mean Titers of Anti-Polio 1, 2, and 3 Antibodies Before and Following A Three-Dose Primary Vaccination series with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis

Vaccine	
End point title	Geometric Mean Titers of Anti-Polio 1, 2, and 3 Antibodies Before and Following A Three-Dose Primary Vaccination series with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis Vaccine

End point description:

Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure.

End point type	Secondary

End point timeframe:

Pre-Primary, Adjusted Pre-Primary, and Post-Primary Vaccination

End point values	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	186	193		
Units: Titers (1/dil)				
geometric mean (confidence interval 95%)				
Anti-Poliovirus 1; Pre-Primary	8.8 (7.5 to 10.4)	9.3 (8 to 10.9)		
Anti-Poliovirus 1; Adjusted Pre-Primary	0.8 (0.7 to 1)	0.8 (0.7 to 1)		
Anti-Poliovirus 1; Post-Primary	151.2 (129.5 to 176.6)	1089.5 (892.1 to 1330.5)		
Anti-Poliovirus 2; Pre-Primary	8.3 (7.1 to 9.7)	7.6 (6.7 to 8.7)		
Anti-Poliovirus 2; Adjusted Pre-Primary	0.8 (0.6 to 0.9)	0.7 (0.6 to 0.8)		
Anti-Poliovirus 2; Post-Primary	86.7 (74.3 to 101.1)	538.2 (470 to 616.3)		
Anti-Poliovirus 3; Pre-Primary	5.2 (4.7 to 5.7)	5.2 (4.8 to 5.7)		
Anti-Poliovirus 3; Adjusted Pre-Primary	0.5 (0.4 to 0.5)	0.5 (0.4 to 0.5)		
Anti-Poliovirus 3; Post-Primary	211.3 (179.6 to 248.6)	203.7 (167.9 to 247.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titer Ratios of Anti-polio 1, 2, and 3 Antibodies Following A Three-Dose Primary Vaccination series with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis Vaccine

End point title	Geometric Mean Titer Ratios of Anti-polio 1, 2, and 3 Antibodies Following A Three-Dose Primary Vaccination series with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis Vaccine

End point description:

Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure. Geometric mean titer ratios (GMTR) and adjusted GMTR are reported. Adjusted was defined as a 4-fold increase calculated with individual titers adjusted on the level of maternal anti-Polio antibodies in subjects' serum at V01 and their estimated levels that would have been observed at V04 if vaccination had not been performed.

End point type	Secondary

End point timeframe:

Day 0 (pre-vaccination) and Day 30 post-primary vaccinations

End point values	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	186	193		
Units: Titer ratios (1/dil)				
geometric mean (confidence interval 95%)				
Anti-Poliovirus 1; Individual Ratio	17.1 (13.5 to 21.7)	119.4 (92.4 to 154.4)		
Anti-Poliovirus 1; Individual Adjusted Ratio	187.1 (147.8 to 236.9)	1309 (1012.6 to 1692.2)		
Anti-Poliovirus 2; Individual Ratio	10.4 (8.2 to 13.2)	70.8 (58.9 to 85)		
Anti-Poliovirus 2; Individual Adjusted Ratio	113.4 (89.4 to 143.9)	774.8 (643.3 to 933.1)		
Anti-Poliovirus 3; Individual Ratio	40.9 (33.6 to 49.8)	38.6 (31.2 to 47.9)		
Anti-Poliovirus 3; Individual Adjusted Ratio	446.9 (367.1 to 544)	422.9 (341.2 to 524.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Infant Subjects with Seroprotection Against poliovirus 1, 2 and 3 Before and Following A Three-Dose Primary Vaccination series with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis Vaccine

End point title	Percentage of Infant Subjects with Seroprotection Against poliovirus 1, 2 and 3 Before and Following A Three-Dose Primary Vaccination series with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis Vaccine

End point description:

Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure. Seroprotection was defined as Anti-Poliovirus type 1, 2, and 3 antibody titers ≥ 8 (1/dil).

End point type	Secondary

End point timeframe:

Pre-Primary, Adjusted Pre-Primary, Post-Primary Vaccination

End point values	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	186	193		
Units: Percentage of subjects				
number (not applicable)				
Anti-Poliovirus 1; Pre-Primary	44.8	47.6		
Anti-Poliovirus 1; Adjusted Pre-Primary	5.5	5.2		
Anti-Poliovirus 1; Post-Primary	100	97.4		
Anti-Poliovirus 2; Pre-Primary	39.2	40.3		
Anti-Poliovirus 2; Adjusted Pre-Primary	4.4	1.6		
Anti-Poliovirus 2; Post-Primary	97.3	100		
Anti-Poliovirus 3; Pre-Primary	18.2	17.3		
Anti-Poliovirus 3; Adjusted Pre-Primary	0	0.5		
Anti-Poliovirus 3; Post-Primary	98.9	95.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Infant Subjects with ≥4-fold increase in Antibodies Against Poliovirus 1, 2 and 3 After A Three-Dose Primary Vaccination series with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio) or Commercially Available Oral Poliomyelitis Vaccine

End point title	Percentage of Infant Subjects with ≥4-fold increase in Antibodies Against Poliovirus 1, 2 and 3 After A Three-Dose Primary Vaccination series with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio) or Commercially Available Oral Poliomyelitis Vaccine

End point description:

Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure. A 4-fold increase was calculated with individual titers adjusted on the level of maternal anti-Polio antibodies in subjects' serum at V01 and their estimated levels that would have been observed at V04 if vaccination had not been performed.

End point type	Secondary

End point timeframe:

Post-Primary/Pre-Primary Vaccination

End point values	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	186	193		
Units: Percentage of subjects				
number (not applicable)				
Anti-Poliovirus 1; Individual Ratio	85.1	93.2		
Anti-Poliovirus 1; Individual Adjusted Ratio	98.3	98.4		
Anti-Poliovirus 2; Individual Ratio	75.7	97.9		

Anti-Poliovirus 2; Individual Adjusted Ratio	93.9	100		
Anti-Poliovirus 3; Individual Ratio	95.6	92.1		
Anti-Poliovirus 3; Individual Adjusted Ratio	99.4	97.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Anti-Polio 1, 2, and 3 Antibodies in Subjects with Pre-Primary Anti-Polio Titers of < 8 (1/dil) and ≥8 (1/dil) Before and After Primary Vaccination with Inactivated Poliomyelitis Vaccine or Oral Poliomyelitis Vaccine

End point title	Geometric Mean Titers of Anti-Polio 1, 2, and 3 Antibodies in Subjects with Pre-Primary Anti-Polio Titers of < 8 (1/dil) and ≥8 (1/dil) Before and After Primary Vaccination with Inactivated Poliomyelitis Vaccine or Oral Poliomyelitis Vaccine

End point description:

Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure.

End point type	Secondary

End point timeframe:

Pre-Primary and Post-Primary Vaccination

End point values	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	300	300		
Units: Titers (1/dil)				
geometric mean (confidence interval 95%)				
Anti-Poliovirus 1; All Subjects; Pre-Primary	8.8 (7.5 to 10.4)	9.3 (8 to 10.9)		
Anti-Poliovirus 1; All Subjects; Post-Primary	151.2 (129.5 to 176.6)	1089.5 (892.1 to 1330.5)		
Anti-Poliovirus 1; < 8 (1/dil); Pre-Primary	4 (4 to 4)	4 (4 to 4)		
Anti-Poliovirus 1; < 8 (1/dil); Post-Primary	176.1 (144.3 to 214.9)	1116.7 (825.1 to 1511.3)		
Anti-Poliovirus 1; ≥ 8 (1/dil); Pre-Primary	23.6 (18.9 to 29.4)	23.5 (19.3 to 28.6)		
Anti-Poliovirus 1; ≥ 8 (1/dil); Post-Primary	125.9 (97.6 to 162.5)	1068.9 (816.4 to 1399.5)		
Anti-Poliovirus 2; All Subjects; Pre-Primary	8.3 (7.1 to 9.7)	7.6 (6.7 to 8.7)		
Anti-Poliovirus 2; All Subjects; Post-Primary	86.7 (74.3 to 101.1)	538.2 (470 to 616.3)		
Anti-Poliovirus 2; < 8 (1/dil); Pre-Primary	4 (4 to 4)	4 (4 to 4)		
Anti-Poliovirus 2; < 8 (1/dil); Post-Primary	100.3 (83.3 to 120.8)	497.9 (418.5 to 592.4)		

Anti-Poliovirus 2; ≥ 8 (1/dil); Pre-Primary	25.8 (20.6 to 32.3)	19.6 (16.5 to 23.4)		
Anti-Poliovirus 2; ≥ 8 (1/dil); Post-Primary	68.3 (52.6 to 88.7)	601.5 (480.9 to 752.3)		
Anti-Poliovirus 3; All Subjects; Pre-Primary	5.2 (4.7 to 5.7)	5.2 (4.8 to 5.7)		
Anti-Poliovirus 3; All Subjects; Post-Primary	211.3 (179.6 to 248.6)	203.7 (167.9 to 247.1)		
Anti-Poliovirus 3; < 8 (1/dil); Pre-Primary	4 (4 to 4)	4 (4 to 4)		
Anti-Poliovirus 3; < 8 (1/dil); Post-Primary	218.2 (180.7 to 263.4)	202.5 (163.2 to 251.4)		
Anti-Poliovirus 3; ≥ 8 (1/dil); Pre-Primary	17.2 (13.2 to 22.3)	18.8 (14.6 to 24.3)		
Anti-Poliovirus 3; ≥ 8 (1/dil); Post-Primary	194.3 (135.5 to 278.6)	197.5 (122.7 to 317.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titer Ratios of Anti-Polio 1, 2, and 3 Antibodies in Subjects with Pre-Primary Anti-Polio Titers of < 8 (1/dil) and ≥8 (1/dil) After Primary Vaccination with Inactivated Poliomyelitis Vaccine or Oral Poliomyelitis Vaccine

End point title	Geometric Mean Titer Ratios of Anti-Polio 1, 2, and 3 Antibodies in Subjects with Pre-Primary Anti-Polio Titers of < 8 (1/dil) and ≥8 (1/dil) After Primary Vaccination with Inactivated Poliomyelitis Vaccine or Oral Poliomyelitis Vaccine

End point description:

Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure. Geometric mean titer ratios (GMTR) and adjusted GMTR are reported. Adjusted was defined as a 4-fold increase calculated with individual titers adjusted on the level of maternal anti-Polio antibodies in subjects' serum at V01 and their estimated levels that would have been observed at V04 if vaccination had not been performed.

End point type	Secondary

End point timeframe:

Day 0 (pre-vaccination) and Day 30 post-primary vaccinations

End point values	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	300	300		
Units: Titer ratios (1/dil)				
geometric mean (confidence interval 95%)				
Anti-Poliovirus 1; GMTR; All Subjects	17.1 (13.5 to 21.7)	119.4 (92.4 to 154.4)		
Anti-Poliovirus 1; GMTR; < 8 (1/dil)	44 (36.1 to 53.7)	279.2 (206.3 to 377.8)		
Anti-Poliovirus 1; GMTR; ≥ 8 (1/dil)	5.3 (3.9 to 7.4)	47.4 (33.9 to 66.2)		

Anti-Poliovirus 1; Adjusted GMTR; All Subjects	187.1 (147.8 to 236.9)	1309 (1012.6 to 1692.2)		
Anti-Poliovirus 1; Adjusted GMTR; < 8 (1/dil)	477.7 (390.6 to 584.1)	3081.2 (2282.4 to 4159.6)		
Anti-Poliovirus 1; Adjusted GMTR; ≥ 8 (1/dil)	58.8 (42.7 to 81.1)	515.4 (368.6 to 720.6)		
Anti-Poliovirus 2; GMTR; All Subjects	10.4 (8.2 to 13.2)	70.8 (58.9 to 85)		
Anti-Poliovirus 2; GMTR; < 8 (1/dil)	25.1 (20.8 to 30.2)	124.5 (104.6 to 148.1)		
Anti-Poliovirus 2; GMTR; ≥ 8 (1/dil)	2.6 (1.8 to 3.7)	30.7 (22.9 to 41.1)		
Anti-Poliovirus 2; Adjusted GMTR; All Subjects	113.4 (89.4 to 143.9)	774.8 (643.3 to 933.1)		
Anti-Poliovirus 2; Adjusted GMTR; <8 (1/dil)	271.7 (226.3 to 326.2)	1365.6 (1145.3 to 1628.2)		
Anti-Poliovirus 2; Adjusted GMTR; ≥ 8 (1/dil)	28.9 (20.4 to 40.9)	334.8 (248.7 to 450.5)		
Anti-Poliovirus 3; GMTR; All Subjects	40.9 (33.6 to 49.8)	38.6 (31.2 to 47.9)		
Anti-Poliovirus 3; GMTR; < 8 (1/dil)	54.5 (45.2 to 65.9)	50.6 (40.8 to 62.8)		
Anti-Poliovirus 3; GMTR; ≥ 8 (1/dil)	11.3 (6.9 to 18.4)	10.3 (6.2 to 17.3)		
Anti-Poliovirus 3; Adjusted GMTR; All Subjects	446.9 (367.1 to 544)	422.9 (341.2 to 524.1)		
Anti-Poliovirus 3; Adjusted GMTR; < 8 (1/dil)	593.6 (491.5 to 717)	553.7 (446.9 to 685.9)		
Anti-Poliovirus 3; Adjusted GMTR; ≥ 8 (1/dil)	126.1 (77.8 to 204.3)	113.7 (67.5 to 191.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Infant Subjects with Pre-Primary Anti-Polio Titers of < 8 (1/dil) and ≥8 (1/dil) with Seroprotection Against Poliovirus 1, 2 and 3 Before and After Primary Vaccination with Inactivated Poliomyelitis Vaccine or Oral Poliomyelitis Vaccine

End point title	Percentage of Infant Subjects with Pre-Primary Anti-Polio Titers of < 8 (1/dil) and ≥8 (1/dil) with Seroprotection Against Poliovirus 1, 2 and 3 Before and After Primary Vaccination with Inactivated Poliomyelitis Vaccine or Oral Poliomyelitis Vaccine

End point description:

Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure.

End point type	Secondary

End point timeframe:

Pre-Primary and Post-Primary Vaccination

End point values	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	300	300		
Units: Percentage of subjects				
number (not applicable)				
Anti-Poliovirus 1; All Subjects; Pre-Primary	44.8	47.6		
Anti-Poliovirus 1; All Subjects; Post-Primary	100	97.4		
Anti-Poliovirus 1; < 8 (1/dil); Pre-Primary	0	0		
Anti-Poliovirus 1; < 8 (1/dil); Post-Primary	100	96		
Anti-Poliovirus 1; ≥ 8 (1/dil); Pre-Primary	100	100		
Anti-Poliovirus 1; ≥ 8 (1/dil); Post-Primary	100	98.9		
Anti-Poliovirus 2; All Subjects; Pre-Primary	39.2	40.3		
Anti-Poliovirus 2; All Subjects; Post-Primary	97.3	100		
Anti-Poliovirus 2; < 8 (1/dil); Pre-Primary	0	0		
Anti-Poliovirus 2; < 8 (1/dil); Post-Primary	98.2	100		
Anti-Poliovirus 2; ≥ 8 (1/dil); Pre-Primary	100	100		
Anti-Poliovirus 2; ≥ 8 (1/dil); Post-Primary	95.8	100		
Anti-Poliovirus 3; All Subjects; Pre-Primary	18.2	17.3		
Anti-Poliovirus 3; All Subjects; Post-Primary	98.9	95.3		
Anti-Poliovirus 3; < 8 (1/dil); Pre-Primary	0	0		
Anti-Poliovirus 3; < 8 (1/dil); Post-Primary	98.6	95.6		
Anti-Poliovirus 3; ≥ 8 (1/dil); Pre-Primary	100	100		
Anti-Poliovirus 3; ≥ 8 (1/dil); Post-Primary	100	93.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Infant Subjects with Pre-Primary Anti-Polio Titers of < 8 (1/dil) and ≥8 (1/dil) with ≥4-Fold Increase in Antibodies Against Poliovirus 1, 2 and 3 After Primary Vaccination with Inactivated Poliomyelitis Vaccine or Oral Poliomyelitis Vaccine

End point title	Percentage of Infant Subjects with Pre-Primary Anti-Polio Titers of < 8 (1/dil) and ≥8 (1/dil) with ≥4-Fold Increase in Antibodies Against Poliovirus 1, 2 and 3 After Primary Vaccination with Inactivated Poliomyelitis Vaccine or Oral Poliomyelitis Vaccine

End point description:

Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure. Adjusted was defined as a 4-fold increase calculated with individual titers adjusted on the level of maternal anti-Polio antibodies in subjects' serum at V01 and their estimated levels that would have been observed at V04 if vaccination had not been performed.

End point type	Secondary

End point timeframe:

Post-Primary Vaccination

End point values	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	300	300		
Units: Percentage of subjects				
number (not applicable)				
Anti-Poliovirus 1; ≥ 4-fold increase; All Subjects	85.1	93.2		
Anti-Poliovirus 1; ≥ 4-fold increase; < 8 (1/dil)	100	96		
Anti-Poliovirus 1; ≥ 4-fold increase; ≥ 8 (1/dil)	66.7	90.1		
Anti-Polio 1; Adj. ≥ 4-fold increase; All Subjects	98.3	98.4		
Anti-Polio 1; Adj. ≥ 4-fold increase; < 8 (1/dil)	100	98		
Anti-Polio 1; Adj. ≥ 4-fold increase; ≥ 8 (1/dil)	96.3	98.9		
Anti-Poliovirus 2; ≥ 4-fold increase; All Subjects	75.7	97.9		
Anti-Poliovirus 2; ≥ 4-fold increase; < 8 (1/dil)	96.4	100		
Anti-Poliovirus 2; ≥ 4-fold increase; ≥ 8 (1/dil)	43.7	94.8		
Anti-Polio 2; Adj. ≥ 4-fold increase; All Subjects	93.9	100		
Anti-Polio 2; Adj. ≥ 4-fold increase; < 8 (1/dil)	98.2	100		
Anti-Polio 2; Adj. ≥ 4-fold increase; ≥ 8 (1/dil)	87.3	100		
Anti-Poliovirus 3; ≥ 4-fold increase; All Subjects	95.6	92.1		
Anti-Poliovirus 3; ≥ 4-fold increase; < 8 (1/dil)	98	95.6		
Anti-Poliovirus 3; ≥ 4-fold increase; ≥ 8 (1/dil)	84.8	75.8		
Anti-Polio 3; Adj. ≥ 4-fold increase; All Subjects	99.4	97.9		
Anti-Polio 3; Adj. ≥ 4-fold increase; < 8 (1/dil)	99.3	98.7		
Anti-Polio 3; Adj. ≥ 4-fold increase; ≥ 8 (1/dil)	100	93.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Infant Subjects with Seroprotection Against Poliovirus 1, 2 and 3 Post-Primary and Pre-Booster Vaccination with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis Vaccine

End point title	Percentage of Infant Subjects with Seroprotection Against Poliovirus 1, 2 and 3 Post-Primary and Pre-Booster Vaccination with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis Vaccine

End point description:

Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure. Seroprotection was defined as Anti-Poliovirus type 1, 2, and 3 antibody titers ≥ 8 (1/dil).

End point type	Secondary

End point timeframe:

Post-Primary and Pre-Booster Vaccination

End point values	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	179	192		
Units: Percentage of subjects				
number (not applicable)				
Anti-Poliovirus 1; Post-Primary	100	97.4		
Anti-Poliovirus 1; Pre-Booster	88.3	96.9		
Anti-Poliovirus 2; Post-Primary	97.2	100		
Anti-Poliovirus 2; Pre-Booster	83.2	99.5		
Anti-Poliovirus 3; Post-Primary	98.9	94.8		
Anti-Poliovirus 3; Pre-Booster	82.7	91.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Anti-Polio 1, 2, and 3 Antibodies Post-Primary and Pre-Booster Vaccination with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis Vaccine

End point title	Geometric Mean Titers of Anti-Polio 1, 2, and 3 Antibodies Post-Primary and Pre-Booster Vaccination with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis Vaccine

End point description:

Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure.

End point type	Secondary

End point timeframe:

Post-Primary and Pre-Booster Vaccination

End point values	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	179	192		
Units: Titers (1/dil)				
geometric mean (confidence interval 95%)				
Anti-Poliovirus 1; Post-Primary	152.9 (130.2 to 179.5)	1096.2 (896.2 to 1340.8)		
Anti-Poliovirus 1; Pre-Booster	44.3 (35.2 to 55.7)	215.1 (177.1 to 261.2)		
Anti-Poliovirus 2; Post-Primary	86.7 (74.1 to 101.5)	538.7 (470 to 617.4)		
Anti-Poliovirus 2; Pre-Booster	47.3 (34.3 to 65)	175.5 (145 to 212.2)		
Anti-Poliovirus 3; Post-Primary	207.3 (175.8 to 244.4)	196.4 (161 to 239.5)		
Anti-Poliovirus 3; Pre-Booster	45.6 (34.1 to 60.9)	63.3 (51.6 to 77.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titer Ratios of Anti-Polio 1, 2, and 3 Antibodies Post-Primary and Pre-Booster Vaccination with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis Vaccine

End point title	Geometric Mean Titer Ratios of Anti-Polio 1, 2, and 3 Antibodies Post-Primary and Pre-Booster Vaccination with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis Vaccine

End point description:

Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure.

End point type	Secondary

End point timeframe:

Day 0 (pre-vaccination) and Day 30 post-primary vaccinations

End point values	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	179	192		
Units: Titer ratio (1/dil)				
geometric mean (confidence interval 95%)				
Anti-Poliovirus 1	0.3 (0.2 to 0.4)	0.2 (0.2 to 0.2)		

Anti-Poliovirus 2	0.6 (0.4 to 0.8)	0.3 (0.3 to 0.4)		
Anti-Poliovirus 3	0.2 (0.2 to 0.3)	0.3 (0.3 to 0.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Infant Subjects with Seroprotection Against Poliovirus 1, 2 and 3 Post-Primary, Pre- and Post-Booster Vaccination with Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)

End point title	Percentage of Infant Subjects with Seroprotection Against Poliovirus 1, 2 and 3 Post-Primary, Pre- and Post-Booster Vaccination with Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)[4]

End point description:

Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure. Seroprotection was defined as Anti-Poliovirus type 1, 2, and 3 antibody titers ≥ 8 (1/dil).

End point type	Secondary

End point timeframe:

Post-Primary, Pre-Booster, and Post-Booster Vaccination

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: A booster vaccination was not administered in the OPV group; therefore, seroprotection data are not available for this group.

End point values	IMOVAX Polio™ Group			
Subject group type	Reporting group			
Number of subjects analysed	176			
Units: Percentage of subjects				
number (not applicable)				
Anti-Poliovirus 1; Post-Primary	100			
Anti-Poliovirus 1; Pre-Booster	88.1			
Anti-Poliovirus 1; Post-Booster	100			
Anti-Poliovirus 2; Post-Primary	97.2			
Anti-Poliovirus 2; Pre-Booster	83			
Anti-Poliovirus 2; Post-Booster	100			
Anti-Poliovirus 3; Post-Primary	98.9			
Anti-Poliovirus 3; Pre-Booster	82.4			
Anti-Poliovirus 3; Post-Booster	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Anti-Polio 1, 2, and 3 Antibodies Post-Primary, Pre- and Post-Booster Vaccination with Inactivated Poliomyelitis Vaccine (IMOVAX

Polio™)

End point title	Geometric Mean Titers of Anti-Polio 1, 2, and 3 Antibodies Post-Primary, Pre- and Post-Booster Vaccination with Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)[5]

End point description:

Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure.

End point type	Secondary

End point timeframe:

Post-Primary, Pre-Booster, Post-Booster Vaccination

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: A booster vaccination was not administered in the OPV group; therefore, geometric mean titer data are not available for this group.

End point values	IMOVAX Polio™ Group			
Subject group type	Reporting group			
Number of subjects analysed	176			
Units: Titers (1/dil)				
geometric mean (confidence interval 95%)				
Anti-Poliovirus 1; Post-Primary	150.3 (128.5 to 175.7)			
Anti-Poliovirus 1; Pre-Booster	44.5 (35.2 to 56.1)			
Anti-Poliovirus 1; Post-Booster	2011.8 (1762.4 to 2296.6)			
Anti-Poliovirus 2; Post-Primary	85.2 (72.8 to 99.8)			
Anti-Poliovirus 2; Pre-Booster	47.8 (34.6 to 66.2)			
Anti-Poliovirus 2; Post-Booster	1480.6 (1305.6 to 1679.1)			
Anti-Poliovirus 3; Post-Primary	208.9 (176.9 to 246.7)			
Anti-Poliovirus 3; Pre-Booster	45.7 (34 to 61.3)			
Anti-Poliovirus 3; Post-Booster	4393.4 (3849.8 to 5013.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titer Ratios of Anti-Polio 1, 2, and 3 Antibodies Post-Primary and Post-Booster Vaccination with Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)

End point title	Geometric Mean Titer Ratios of Anti-Polio 1, 2, and 3 Antibodies Post-Primary and Post-Booster Vaccination with Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)[6]

End point description:

Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure.

End point type	Secondary

End point timeframe:

Day 0 (pre-vaccination) and Day 30 post-primary vaccinations and Day 0 (pre-vaccination) and Day 30 post-booster vaccination

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: A booster vaccination was not administered in the OPV group; therefore, geometric mean titer ratios data are not available for this group.

End point values	IMOVAX Polio™ Group			
Subject group type	Reporting group			
Number of subjects analysed	176			
Units: Titer ratio (1/dil)				
geometric mean (confidence interval 95%)				
Anti-Poliovirus 1; Post/Pre-Primary	16.6 (13.1 to 21.2)			
Anti-Poliovirus 1; Post/Pre-Booster	45.2 (34.9 to 58.7)			
Anti-Poliovirus 2; Post/Pre-Primary	10.3 (8 to 13.1)			
Anti-Poliovirus 2; Post/Pre-Booster	30.9 (22.5 to 42.6)			
Anti-Poliovirus 3; Post/Pre-Primary	40.7 (33.2 to 49.8)			
Anti-Poliovirus 3; Post/Pre-Booster	96.2 (69.1 to 133.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Infant Subjects with ≥4-Fold Increase in Antibodies Against Poliovirus 1, 2 and 3 Post-Primary and Post-Booster Vaccination with Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)

End point title	Percentage of Infant Subjects with ≥4-Fold Increase in Antibodies Against Poliovirus 1, 2 and 3 Post-Primary and Post-Booster Vaccination with Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)[7]

End point description:

Anti-Poliovirus types 1, 2, and 3 antibody titers were assayed by microneutralization on cell culture based on World Health Organization standardized procedure.

End point type	Secondary

End point timeframe:

Post-Primary and Post-Booster Vaccination

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: A booster vaccination was not administered in the OPV group; therefore, data for subjects with ≥ 4-fold increase in antibodies are not available for this group.

End point values	IMOVAX Polio™ Group			
Subject group type	Reporting group			
Number of subjects analysed	176			
Units: Percentage of subjects				
number (not applicable)				
Anti-Poliovirus 1; Post-Primary	84.2			
Anti-Poliovirus 1; Post-Booster	92			
Anti-Poliovirus 2; Post-Primary	76			
Anti-Poliovirus 2; Post-Booster	83			
Anti-Poliovirus 3; Post-Primary	95.3			
Anti-Poliovirus 3; Post-Booster	89.2			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Infant Subjects with Solicited Injection-site and Systemic Reactions Following Any and Each Primary Series Vaccination with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis Vaccine

End point title	Percentage of Infant Subjects with Solicited Injection-site and Systemic Reactions Following Any and Each Primary Series Vaccination with Either Inactivated Poliomyelitis Vaccine (IMOVAX Polio™) or Commercially Available Oral Poliomyelitis Vaccine

End point description:

Solicited injection site reactions: Tenderness, Erythema, Swelling. Solicited systemic reaction: Fever (as per China State Food and Drug Administration), Vomiting, Crying abnormal, Drowsiness, Appetite lost, Irritability. OPV is an oral vaccine and does not have solicited injection site data.

Grade 3 Solicited injection site reactions: Tenderness, Cries when injected limb is moved or the movement of the injected limb is reduced; Erythema and Swelling, ≥5 cm. Grade 3 Solicited systemic reactions: Fever, >39°C (Axillary); Vomiting, ≥6 episodes per 24 hours or requiring parenteral hydration; Crying abnormal, > 3 hours; Drowsiness, Sleeping most of the time or difficulty in waking up; Appetite lost, Refuses ≥ 3 feeds or refuses most feeds; Irritability; Inconsolable.

End point type	Secondary

End point timeframe:

Day 0 up to Day 8 post-any and each primary vaccination

End point values	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	300	297[8]		
Units: Percentage of subjects				
number (not applicable)				
Any Injection site Tenderness	36.7	0		
Injection site Tenderness; Post-dose 1	27.4	0		
Grade 3 Injection site Tenderness; Post-dose 1	0.3	0		

Injection site Tenderness; Post-dose 2	20.1	0		
Grade 3 Injection site Tenderness; Post-dose 2	0	0		
Injection site Tenderness; Post-dose 3	14.4	0		
Grade 3 Injection site Tenderness; Post-dose 3	0	0		
Any Injection site Erythema	14.8	0		
Injection site Erythema; Post-dose 1	8.4	0		
Grade 3 Injection site Erythema; Post-dose 1	0	0		
Injection site Erythema; Post-dose 2	7.6	0		
Grade 3 Injection site Erythema; Post-dose 2	0	0		
Injection site Erythema; Post-dose 3	6.8	0		
Grade 3 Injection site Erythema; Post-dose 3	0.4	0		
Any Injection site Swelling	4.7	0		
Injection site Swelling; Post-dose 1	4.1	0		
Grade 3 Injection site Swelling; Post-dose 1	0	0		
Injection site Swelling; Post-dose 2	1.1	0		
Grade 3 Injection site Swelling; Post-dose 2	0	0		
Injection site Swelling; Post-dose 3	0.7	0		
Grade 3 Injection site Swelling; Post-dose 3	0	0		
Any Fever	25.9	25		
Fever; Post-dose 1	15.2	10.3		
Grade 3 Fever; Post-dose 1	0	0.3		
Fever; Post-dose 2	10	8.5		
Grade 3 Fever; Post-dose 2	0	0.4		
Fever; Post-dose 3	6.5	12.1		
Grade 3 Fever; Post-dose 3	0.4	0		
Any Vomiting	43.7	39.7		
Vomiting; Post-dose 1	36.1	30.1		
Grade 3 Vomiting; Post-dose 1	0.3	0.7		
Vomiting; Post-dose 2	22.5	17.6		
Grade 3 Vomiting; Post-dose 2	0	0		
Vomiting; Post-dose 3	12.2	11.3		
Grade 3 Vomiting; Post-dose 3	0.4	0		
Any Crying abnormal	46.1	29.1		
Crying abnormal; Post-dose 1	35.7	22.9		
Grade 3 Crying abnormal; Post-dose 1	2	1.4		
Crying abnormal; Post-dose 2	24.3	10.6		
Grade 3 Crying abnormal; Post-dose 2	0.7	1.1		
Crying abnormal; Post-dose 3	12.2	8.9		
Grade 3 Crying abnormal; Post-dose 3	0	0		
Any Drowsiness	31.9	19.5		
Drowsiness; Post-dose 1	25.9	17.5		
Grade 3 Drowsiness; Post-dose 1	1.7	1		
Drowsiness; Post-dose 2	11.1	4.6		
Grade 3 Drowsiness; Post-dose 2	0	0.4		
Drowsiness; Post-dose 3	6.1	3.2		
Grade 3 Drowsiness; Post-dose 3	0	0		

Any Appetite lost	30.2	21.9		
Appetite lost; Post-dose 1	24.1	15.4		
Grade 3 Appetite lost; Post-dose 1	1	1		
Appetite lost; Post-dose 2	14.3	8.1		
Grade 3 Appetite lost; Post-dose 2	0	0.4		
Appetite lost; Post-dose 3	8.3	9.2		
Grade 3 Appetite lost; Post-dose 3	0	0.4		
Any Irritability	32.2	18.8		
Irritability; Post-dose 1	24.1	16.8		
Grade 3 Irritability; Post-dose 1	0.7	2.4		
Irritability; Post-dose 2	16.1	6.3		
Grade 3 Irritability; Post-dose 2	0.7	1.1		
Irritability; Post-dose 3	9.4	3.9		
Grade 3 Irritability; Post-dose 3	0.4	0		

Notes:

[8] - N=0 for solicited injection site reactions because Oral Polio Vaccine (OPV) was administered.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Infant Subjects with Solicited Injection-site and Systemic Reactions Following Booster Vaccination with Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)

End point title	Percentage of Infant Subjects with Solicited Injection-site and Systemic Reactions Following Booster Vaccination with Inactivated Poliomyelitis Vaccine (IMOVAX Polio™)[9]

End point description:

Solicited injection site reactions: Tenderness, Erythema, Swelling. Solicited systemic reaction: Fever (as per China State Food and Drug Administration), Vomiting, Crying abnormal, Drowsiness, Appetite lost, Irritability. OPV was not administered as a booster vaccination and data is not available for this group.

Grade 3 Solicited injection site reactions: Tenderness, Cries when injected limb is moved or the movement of the injected limb is reduced; Erythema and Swelling, ≥5 cm. Grade 3 Solicited systemic reactions: Fever, >39°C (Axillary); Vomiting, ≥6 episodes per 24 hours or requiring parenteral hydration; Crying abnormal, > 3 hours; Drowsiness, Sleeping most of the time or difficulty in waking up; Appetite lost, Refuses ≥ 3 feeds or refuses most feeds; Irritability; Inconsolable.

End point type	Secondary

End point timeframe:

Day 0 up to Day 8 post-booster vaccination

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: A booster vaccination was not administered in the OPV group; therefore, solicited injection site and systemic reaction data are not available for this group.

End point values	IMOVAX Polio™ Group			
Subject group type	Reporting group			
Number of subjects analysed	300			
Units: Percentage of subjects				
number (not applicable)				
Any Injection site Tenderness	20			
Grade 3 Injection site Tenderness	0			
Any Injection site Erythema	7.9			

Grade 3 Injection site Erythema	0			
Any Injection site Swelling	2.3			
Grade 3 Injection site Swelling	0			
Any Fever	14.7			
Grade 3 Fever	1.5			
Any Vomiting	3.4			
Grade 3 Vomiting	0			
Any Crying abnormal	10.2			
Grade 3 Crying abnormal	0			
Any Drowsiness	6.4			
Grade 3 Drowsiness	0			
Any Appetite lost	8.6			
Grade 3 Appetite lost	0			
Any Irritability	9.8			
Grade 3 Irritability	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse event data were collected from Day 0 of primary series vaccination up to Day 8 post-booster vaccination.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	7.1

Reporting groups

Reporting group title	IMOVAX Polio™ Group

Reporting group description:

Infants received the IMOVAX Polio™ (IPV) vaccine at 2, 3, and 4 months of age and a booster dose of IPV vaccine 14-16 months after the three-dose primary vaccination.

Reporting group title	Oral Poliomyelitis Vaccine Group

Reporting group description:

Infants received the commercially available Oral Poliomyelitis Vaccine (OPV) vaccine at 2, 3, and 4 months of age.

Serious adverse events	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 300 (3.00%)	7 / 297 (2.36%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	3 / 300 (1.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Animal scratch			
subjects affected / exposed	3 / 300 (1.00%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Dysentery			
subjects affected / exposed	0 / 300 (0.00%)	1 / 297 (0.34%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Infections and infestations			
Pneumonia			
subjects affected / exposed	2 / 300 (0.67%)	2 / 297 (0.67%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis and cellulitis			
subjects affected / exposed	1 / 300 (0.33%)	0 / 297 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 300 (0.00%)	2 / 297 (0.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis (viral)			
subjects affected / exposed	0 / 300 (0.00%)	1 / 297 (0.34%)	
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	IMOVAX Polio™ Group	Oral Poliomyelitis Vaccine Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	136 / 300 (45.33%)	116 / 297 (39.06%)	
Nervous system disorders			
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed[1]	94 / 295 (31.86%)	57 / 292 (19.52%)	
occurrences (all)	94	57	
General disorders and administration site conditions			
Injection site Tenderness			
alternative assessment type: Systematic			
subjects affected / exposed[2]	109 / 297 (36.70%)	0 / 292 (0.00%)	
occurrences (all)	109	0	
Injection site Erythema			
alternative assessment type: Systematic			

subjects affected / exposed[3]	44 / 297 (14.81%)	0 / 292 (0.00%)	
occurrences (all)	44	0	
Injection site Swelling			
alternative assessment type: Systematic			
subjects affected / exposed[4]	14 / 297 (4.71%)	0 / 292 (0.00%)	
occurrences (all)	14	0	
Fever			
alternative assessment type: Systematic			
subjects affected / exposed[5]	77 / 297 (25.93%)	73 / 292 (25.00%)	
occurrences (all)	77	73	
Gastrointestinal disorders			
Vomiting			
alternative assessment type: Systematic			
subjects affected / exposed[6]	129 / 295 (43.73%)	116 / 292 (39.73%)	
occurrences (all)	129	116	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed[7]	25 / 297 (8.42%)	17 / 292 (5.82%)	
occurrences (all)	25	17	
Psychiatric disorders			
Crying abnormal			
alternative assessment type: Systematic			
subjects affected / exposed[8]	136 / 295 (46.10%)	85 / 292 (29.11%)	
occurrences (all)	136	85	
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed[9]	95 / 295 (32.20%)	55 / 292 (18.84%)	
occurrences (all)	95	55	
Metabolism and nutrition disorders			
Appetite lost			
alternative assessment type: Systematic			
subjects affected / exposed[10]	89 / 295 (30.17%)	64 / 292 (21.92%)	
occurrences (all)	89	64	

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: This was a solicited adverse event recorded in a diary card within 8 days post-any primary series injection; the total number (N) reflects those subjects for which the diary cards were returned and for which data were available for the event during the period.

[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: This was a solicited adverse event recorded in a diary card within 8 days post-any primary series injection; the total number (N) reflects those subjects for which the diary cards were returned and for which data were available for the event during the period.

[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: This was a solicited adverse event recorded in a diary card within 8 days post-any primary series injection; the total number (N) reflects those subjects for which the diary cards were returned and for which data were available for the event during the period.

[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: This was a solicited adverse event recorded in a diary card within 8 days post-any primary series injection; the total number (N) reflects those subjects for which the diary cards were returned and for which data were available for the event during the period.

[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: This was a solicited adverse event recorded in a diary card within 8 days post-any primary series injection; the total number (N) reflects those subjects for which the diary cards were returned and for which data were available for the event during the period.

[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: This was a solicited adverse event recorded in a diary card within 8 days post-any primary series injection; the total number (N) reflects those subjects for which the diary cards were returned and for which data were available for the event during the period.

[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: This was an unsolicited adverse event that occurred within 8 days post-any primary series injection; the total number (N) reflects those subjects for which data were available for the event during the period.

[8] - 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: This was a solicited adverse event recorded in a diary card within 8 days post-any primary series injection; the total number (N) reflects those subjects for which the diary cards were returned and for which data were available for the event during the period.

[9] - 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: This was a solicited adverse event recorded in a diary card within 8 days post-any primary series injection; the total number (N) reflects those subjects for which the diary cards were returned and for which data were available for the event during the period.

[10] - 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: This was a solicited adverse event recorded in a diary card within 8 days post-any primary series injection; the total number (N) reflects those subjects for which the diary cards were returned and for which data were available for the event during the period.

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