



## Clinical trial results:

### A Phase 3 Randomized, Open-Label, Clinical Trial to Study the Immunogenicity and Safety of Concomitant and Non-Concomitant Administration of V260 and Inactivated Poliomyelitis Vaccine (IPV) in Chinese Healthy Infants

#### Summary

EudraCT number	2020-003329-49
Trial protocol	Outside EU/EEA
Global end of trial date	08 May 2021

#### Results information

Result version number	v2 (current)
This version publication date	27 April 2023
First version publication date	21 January 2023
Version creation reason	

#### Trial information

##### Trial identification

Sponsor protocol code	V260-074
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04481191
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	Merck Sharp & Dohme LLC
Sponsor organisation address	126 East Lincoln Avenue, P.O. Box 2000, Rahway, NJ, United States, 07065
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@merck.com

Notes:

#### Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	08 May 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 May 2021
Global end of trial reached?	Yes
Global end of trial date	08 May 2021
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

This study will evaluate the immunogenicity and safety of concomitant administration of RotaTeq® (V260) and inactivated poliomyelitis vaccine (IPV) in Chinese infants. Its primary objective is to demonstrate that the immunogenicity of IPV in the concomitant-use group is non-inferior to the immunogenicity of IPV in the staggered-use group. The hypothesis to be tested is: The seroconversion percentage at 1 month post dose 3 for poliovirus types 1, 2, and 3 in the concomitant-use group is non-inferior to those of the staggered-use group.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 August 2020
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: 400
Worldwide total number of subjects	400
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)	400
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
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## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Healthy Chinese infants age 48-63 days were enrolled.

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Concomitant RotaTeq and IPV

Arm description:

Participants received RotaTeq (2 mL oral dose) and IPV (0.5 mL intramuscular [IM] injection ) concomitantly at Visit 2 (15 to 21 days after Visit 1 [Day 1]), Visit 4 (30 to 42 days after Visit 2), and Visit 6 (30 to 42 days after Visit 4).

Arm type	Experimental
Investigational medicinal product name	Inactivated Poliomyelitis Vaccine
Investigational medicinal product code	
Other name	IPV
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL dose IPV (Sabin strain based), administered via IM injection.

Investigational medicinal product name	RotaTeq
Investigational medicinal product code	
Other name	V260
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Live, pentavalent rotavirus vaccine administered as a 2 mL-dose oral solution.

<b>Arm title</b>	Staggered RotaTeq and IPV
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Arm description:

Participants received RotaTeq (2 mL oral dose) at Visit 1 (Day 1), Visit 3 (30 to 42 days after Visit 1), and Visit 5 (30 to 42 days after Visit 3); and IPV (0.5 mL IM injection) at Visit 2 (15 to 21 days after Visit 1), Visit 4 (30 to 42 days after Visit 2), and Visit 6 (30 to 42 days after Visit 4).

Arm type	Active comparator
Investigational medicinal product name	Inactivated Poliomyelitis Vaccine
Investigational medicinal product code	
Other name	IPV
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL dose IPV (Sabin strain based), administered via IM injection.

Investigational medicinal product name	RotaTeq
Investigational medicinal product code	
Other name	V260

Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

Live, pentavalent rotavirus vaccine administered as a 2 mL-dose oral solution.

<b>Number of subjects in period 1</b>	Concomitant RotaTeq and IPV	Staggered RotaTeq and IPV
Started	200	200
≥ 1 V260 Vaccination	189	200
Completed	185	190
Not completed	15	10
Withdrawn by parent/guardian	15	10

## Baseline characteristics

### Reporting groups

Reporting group title	Concomitant RotaTeq and IPV
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Reporting group description:

Participants received RotaTeq (2 mL oral dose) and IPV (0.5 mL intramuscular [IM] injection ) concomitantly at Visit 2 (15 to 21 days after Visit 1 [Day 1]), Visit 4 (30 to 42 days after Visit 2), and Visit 6 (30 to 42 days after Visit 4).

Reporting group title	Staggered RotaTeq and IPV
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Reporting group description:

Participants received RotaTeq (2 mL oral dose) at Visit 1 (Day 1), Visit 3 (30 to 42 days after Visit 1), and Visit 5 (30 to 42 days after Visit 3); and IPV (0.5 mL IM injection) at Visit 2 (15 to 21 days after Visit 1), Visit 4 (30 to 42 days after Visit 2), and Visit 6 (30 to 42 days after Visit 4).

Reporting group values	Concomitant RotaTeq and IPV	Staggered RotaTeq and IPV	Total
Number of subjects	200	200	400
Age categorical Units: Subjects			
Infants and toddlers (48 days - 63 days)	200	200	400
Age continuous Units: days			
arithmetic mean	53.3	53.3	
standard deviation	± 4.8	± 4.6	-
Gender categorical Units: Subjects			
Female	86	93	179
Male	114	107	221
Race Units: Subjects			
Asian	200	200	400

## End points

### End points reporting groups

Reporting group title	Concomitant RotaTeq and IPV
Reporting group description: Participants received RotaTeq (2 mL oral dose) and IPV (0.5 mL intramuscular [IM] injection ) concomitantly at Visit 2 (15 to 21 days after Visit 1 [Day 1]), Visit 4 (30 to 42 days after Visit 2), and Visit 6 (30 to 42 days after Visit 4).	
Reporting group title	Staggered RotaTeq and IPV
Reporting group description: Participants received RotaTeq (2 mL oral dose) at Visit 1 (Day 1), Visit 3 (30 to 42 days after Visit 1), and Visit 5 (30 to 42 days after Visit 3); and IPV (0.5 mL IM injection) at Visit 2 (15 to 21 days after Visit 1), Visit 4 (30 to 42 days after Visit 2), and Visit 6 (30 to 42 days after Visit 4).	

### Primary: Percentage of Participants Achieving Neutralizing Antibody Seroconversion to Poliovirus Types 1, 2, and 3 at 1 Month Post Dose 3 of IPV

End point title	Percentage of Participants Achieving Neutralizing Antibody Seroconversion to Poliovirus Types 1, 2, and 3 at 1 Month Post Dose 3 of IPV
End point description: The immunogenicity of IPV was measured using poliovirus serum neutralizing antibody assay of the National Institutes for Food and Drug Control (NIFDC), Beijing, China. Serum conversion was defined as antibody titer $\geq 1:8$ post-vaccination in baseline seronegative participants or $\geq 4$ -fold increase in titer post-vaccination in baseline seropositive participants. Participants who received the 3 scheduled doses of study vaccination, adhered to guidelines for vaccine administration, provided baseline and post-vaccination blood samples within the acceptable day range, and did not have important protocol deviations are included.	
End point type	Primary
End point timeframe: Baseline and 1 month postdose 3 of IPV (Month ~3.5)	

End point values	Concomitant RotaTeq and IPV	Staggered RotaTeq and IPV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	180	187		
Units: Percentage of Participants				
number (not applicable)				
Poliovirus Type 1	98.9	100.0		
Poliovirus Type 2	98.3	99.5		
Poliovirus Type 3	100.0	99.5		

### Statistical analyses

Statistical analysis title	Poliovirus Type 1 Group Difference
Statistical analysis description: Difference indicates Concomitant-use Group % - Staggered-use Group %	

Comparison groups	Staggered RotaTeq and IPV v Concomitant RotaTeq and IPV
Number of subjects included in analysis	367
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[1]</sup>
P-value	< 0.001 <sup>[2]</sup>
Method	Unstratified Miettinen & Nurminen method
Parameter estimate	Mean difference (final values)
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4
upper limit	0.9

Notes:

[1] - Non-inferiority was declared when the lower bound of the 95% CI for the difference in percentages (Concomitant-use Group - Staggered-use Group) being > -10 percentage points (one-sided p-value < 0.025).

[2] - One-sided p-value

<b>Statistical analysis title</b>	Poliovirus Type 3 Group Difference
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Statistical analysis description:

Difference indicates Concomitant-use % - Staggered-use %

Comparison groups	Concomitant RotaTeq and IPV v Staggered RotaTeq and IPV
Number of subjects included in analysis	367
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[3]</sup>
P-value	< 0.001 <sup>[4]</sup>
Method	Unstratified Miettinen & Nurminen method
Parameter estimate	Mean difference (final values)
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	3

Notes:

[3] - Non-inferiority was declared when the lower bound of the 95% CI for the difference in percentages (Concomitant-use Group - Staggered-use Group) being > -10 percentage points (one-sided p-value < 0.025).

[4] - One-sided p-value

<b>Statistical analysis title</b>	Poliovirus Type 2 Group Difference
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Statistical analysis description:

Difference indicates Concomitant-use Group % - Staggered-use Group %

Comparison groups	Concomitant RotaTeq and IPV v Staggered RotaTeq and IPV
Number of subjects included in analysis	367
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[5]</sup>
P-value	< 0.001 <sup>[6]</sup>
Method	Unstratified Miettinen & Nurminen method
Parameter estimate	Mean difference (final values)
Point estimate	-1.1



Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.3
upper limit	1.5

Notes:

[5] - Non-inferiority was declared when the lower bound of the 95% CI for the difference in percentages (Concomitant-use Group - Staggered-use Group) being > -10 percentage points (one-sided p-value < 0.025).

[6] - One-sided p-value

### Secondary: Geometric Mean Titers (GMTs) of Neutralizing Antibody to Poliovirus Types 1, 2, and 3 at 1 Month Post Dose 3 of IPV

End point title	Geometric Mean Titers (GMTs) of Neutralizing Antibody to Poliovirus Types 1, 2, and 3 at 1 Month Post Dose 3 of IPV
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End point description:

The immune response to IPV was measured using poliovirus serum neutralizing antibody assay of the NIFDC, Beijing, China. Participants who received the 3 scheduled doses of study vaccination, adhered to guidelines for vaccine administration, provided baseline and post-vaccination blood samples within the acceptable day range, and did not have important protocol deviations are included.

End point type	Secondary
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End point timeframe:

1 month postdose 3 of IPV (Month ~3.5)

End point values	Concomitant RotaTeq and IPV	Staggered RotaTeq and IPV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	180	187		
Units: Titers				
geometric mean (confidence interval 95%)				
Poliovirus Type 1	5600.80 (4898.46 to 6403.85)	5344.24 (4657.51 to 6132.22)		
Poliovirus Type 2	1059.83 (951.13 to 1180.96)	1122.43 (1002.74 to 1256.41)		
Poliovirus Type 3	3405.56 (3033.93 to 3822.71)	3261.69 (2913.70 to 3651.24)		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants Achieving Neutralizing Antibody Titers ≥1:8 for Poliovirus Types 1, 2, and 3 at 1 Month Post Dose 3 of IPV

End point title	Percentage of Participants Achieving Neutralizing Antibody Titers ≥1:8 for Poliovirus Types 1, 2, and 3 at 1 Month Post Dose 3 of IPV
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End point description:

The immune response to IPV was measured using poliovirus serum neutralizing antibody assay of the NIFDC, Beijing, China. Participants who received the 3 scheduled doses of study vaccination, adhered to guidelines for vaccine administration, provided baseline and post-vaccination blood samples within the acceptable day range, and did not have important protocol deviations are included.

End point type Secondary

End point timeframe:

1 month post dose 3 of IPV (Month ~3.5)

End point values	Concomitant RotaTeq and IPV	Staggered RotaTeq and IPV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	180	187		
Units: Percentage of Participants				
number (confidence interval 95%)				
Poliovirus Type 1	100.0 (98.0 to 100.0)	100.0 (98.0 to 100.0)		
Poliovirus Type 2	100.0 (98.0 to 100.0)	100.0 (98.0 to 100.0)		
Poliovirus Type 3	100.0 (98.0 to 100.0)	100.0 (98.0 to 100.0)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Achieving Neutralizing Antibody Titers $\geq 1:64$ for Poliovirus Types 1, 2, and 3 at 1 Month Post Dose 3 of IPV

End point title Percentage of Participants Achieving Neutralizing Antibody Titers  $\geq 1:64$  for Poliovirus Types 1, 2, and 3 at 1 Month Post Dose 3 of IPV

End point description:

The immune response to IPV was measured using poliovirus serum neutralizing antibody assay of the NIFDC, Beijing, China. Participants who received the 3 scheduled doses of study vaccination, adhered to guidelines for vaccine administration, provided baseline and post-vaccination blood samples within the acceptable day range, and did not have important protocol deviations are included.

End point type Secondary

End point timeframe:

1 month postdose 3 of IPV (Month ~3.5)

End point values	Concomitant RotaTeq and IPV	Staggered RotaTeq and IPV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	180	187		
Units: Percentage of Participants				
number (confidence interval 95%)				

Poliovirus Type 1	100.00 (98.0 to 100.0)	100.0 (98.0 to 100.0)		
Poliovirus Type 2	100.0 (98.0 to 100.0)	100.0 (98.0 to 100.0)		
Poliovirus Type 3	100.0 (98.0 to 100.0)	100.0 (98.0 to 100.0)		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants With Solicited Injection-Site Adverse Events

End point title	Percentage of Participants With Solicited Injection-Site Adverse Events
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End point description:

Solicited injection-site adverse events (AEs) included erythema, swelling, induration, and pain at the IPV injection-site. All participants who received  $\geq 1$  dose of study treatment are included.

End point type	Secondary
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End point timeframe:

Up to 7 days following each IPV vaccination

End point values	Concomitant RotaTeq and IPV	Staggered RotaTeq and IPV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	200		
Units: Percentage of Participants				
number (not applicable)	25.4	23.0		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants With Solicited Systemic Adverse Events

End point title	Percentage of Participants With Solicited Systemic Adverse Events
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End point description:

Solicited systemic AEs included diarrhea, vomiting, and elevated temperature (axillary temperature  $\geq 37.5^\circ \text{C}$ ). All participants who received  $\geq 1$  dose of study treatment are included.

End point type	Secondary
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End point timeframe:

Up to 7 days following each RotaTeq and/or IPV vaccination

End point values	Concomitant RotaTeq and IPV	Staggered RotaTeq and IPV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	200		
Units: Percentage of Participants				
number (not applicable)				
Elevated temperature	12.3	16.3		
Diarrhoea	13.2	21.5		
Vomiting	10.6	19.5		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants With Serious Adverse Events (SAEs)

End point title	Percentage of Participants With Serious Adverse Events (SAEs)
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End point description:

The percentage of participants with SAEs is presented. An SAE is an AE that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or another important medical event. All participants who received  $\geq 1$  dose of study treatment are included.

End point type	Secondary
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End point timeframe:

Up to approximately 3.5 months

End point values	Concomitant RotaTeq and IPV	Staggered RotaTeq and IPV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	200		
Units: Percentage of Participants				
number (not applicable)	3.7	5.5		

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Up to approximately 3.5 months

Adverse event reporting additional description:

All participants who received  $\geq 1$  study-related vaccination are included.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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### Reporting groups

Reporting group title	Staggered RotaTeq and IPV
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Reporting group description:

Participants will receive RotaTeq (2 mL oral dose) at Visit 1 (Day 1), Visit 3 (30 to 42 days after Visit 1), and Visit 5 (30 to 42 days after Visit 3); and IPV (0.5 mL IM injection) at Visit 2 (15 to 21 days after Visit 1), Visit 4 (30 to 42 days after Visit 2), and Visit 6 (30 to 42 days after Visit 4).

Reporting group title	Concomitant RotaTeq and IPV
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Reporting group description:

Participants will receive RotaTeq (2 mL oral dose) and IPV (0.5 mL intramuscular [IM] injection ) concomitantly at Visit 2 (15 to 21 days after Visit 1 [Day 1]), Visit 4 (30 to 42 days after Visit 2), and Visit 6 (30 to 42 days after Visit 4).

Serious adverse events	Staggered RotaTeq and IPV	Concomitant RotaTeq and IPV	
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 200 (5.50%)	7 / 189 (3.70%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Nervous system disorders			
Motor developmental delay			
subjects affected / exposed	0 / 200 (0.00%)	1 / 189 (0.53%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Enteritis			
subjects affected / exposed	1 / 200 (0.50%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Laryngeal obstruction			

subjects affected / exposed	1 / 200 (0.50%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 200 (0.00%)	3 / 189 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	1 / 200 (0.50%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal viral infection			
subjects affected / exposed	1 / 200 (0.50%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	1 / 200 (0.50%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	6 / 200 (3.00%)	3 / 189 (1.59%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	1 / 200 (0.50%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	1 / 200 (0.50%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			

subjects affected / exposed	1 / 200 (0.50%)	0 / 189 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

<b>Non-serious adverse events</b>	Staggered RotaTeq and IPV	Concomitant RotaTeq and IPV	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	143 / 200 (71.50%)	123 / 189 (65.08%)	
General disorders and administration site conditions			
Injection site erythema			
subjects affected / exposed	41 / 200 (20.50%)	45 / 189 (23.81%)	
occurrences (all)	45	62	
Injection site pain			
subjects affected / exposed	7 / 200 (3.50%)	12 / 189 (6.35%)	
occurrences (all)	7	14	
Pyrexia			
subjects affected / exposed	37 / 200 (18.50%)	30 / 189 (15.87%)	
occurrences (all)	48	33	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	50 / 200 (25.00%)	33 / 189 (17.46%)	
occurrences (all)	77	43	
Dyspepsia			
subjects affected / exposed	13 / 200 (6.50%)	10 / 189 (5.29%)	
occurrences (all)	14	13	
Vomiting			
subjects affected / exposed	39 / 200 (19.50%)	20 / 189 (10.58%)	
occurrences (all)	66	23	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	14 / 200 (7.00%)	19 / 189 (10.05%)	
occurrences (all)	16	26	
Rhinorrhoea			

subjects affected / exposed occurrences (all)	18 / 200 (9.00%) 20	17 / 189 (8.99%) 18	
Skin and subcutaneous tissue disorders Eczema subjects affected / exposed occurrences (all)	12 / 200 (6.00%) 18	14 / 189 (7.41%) 14	
Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all)  Bronchitis subjects affected / exposed occurrences (all)  Nasopharyngitis subjects affected / exposed occurrences (all)	36 / 200 (18.00%) 41  13 / 200 (6.50%) 14  14 / 200 (7.00%) 16	31 / 189 (16.40%) 40  8 / 189 (4.23%) 9  14 / 189 (7.41%) 14	



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 January 2020	Amendment 01: The primary purpose was to align protocol with new guideline on the grading scales for adverse events in vaccine studies in China.
11 August 2020	Amendment 2: The primary purpose was to add the EudraCT number and clarify baseline characteristics to be collected.

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Protocol Amendment 3 was issued after study completion. The purpose of the amendment was to update the Sponsor entity name and address.
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Notes: