Clinical trial results:
A Phase 2, partial blind, randomized, placebo-controlled, multicenter study to evaluate the safety and immunogenicity of two novel live attenuated serotype 2 oral poliovirus vaccines candidates, in healthy adults previously vaccinated with oral polio vaccine (OPV) or inactivated polio vaccine (IPV), compared with historical controls given Sabin OPV2 or placebo.

Summary

EudraCT number	2018-001684-22
Trial protocol	BE
Global end of trial date	08 May 2019

Results information

Result version number	v1 (current)
This version publication date	26 June 2022
First version publication date	26 June 2022

Trial information

Trial identification

Sponsor protocol code	UAM4

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04544787
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of Antwerp
Sponsor organisation address	Universiteitsplein 1, Wilrijk, Belgium, 2610
Public contact	Prof.Dr.PhD. Pierre Van Damme, University of Antwerp, +32 (0)32652538, pierre.vandamme@uantwerpen.be
Scientific contact	Prof.Dr.PhD. Pierre Van Damme, University of Antwerp, +32 (0)32652538, pierre.vandamme@uantwerpen.be

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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	08 May 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 May 2019
Global end of trial reached?	Yes
Global end of trial date	08 May 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of the study are
- To assess the safety (serious adverse events [SAEs] and severe adverse events [AEs]) of novel monovalent live attenuated oral serotype 2 poliovirus vaccine (nOPV2) candidate 1 and novel monovalent live attenuated oral serotype 2 poliovirus vaccine (nOPV2) candidate 2 in healthy OPV-vaccinated adults, relative to historical controls given Sabin OPV2;
- To compare the immunogenicity (seroprotection rate) of novel monovalent live attenuated oral serotype 2 poliovirus vaccine (nOPV2) candidate 1 and novel monovalent live attenuated oral serotype 2 poliovirus vaccine (nOPV2) candidate 2 in healthy OPV-vaccinated adults to historical controls given Sabin OPV2;
- To assess the safety (serious adverse events [SAEs] and severe adverse events [AEs]) of nOPV2 candidate 1 and nOPV2 candidate 2 in healthy IPV-only vaccinated adults, compared with placebo.

Protection of trial subjects:

To reduce the likelihood that nOPV2 candidate vaccine strains or their genetic variants could be transmitted to unintended recipients who are not vaccinated for polio or who are immunocompromised, study subjects were only eligible for inclusion in the study if they
-have received at least 3 doses of OPV or IPV in the past.
-have their residence in Belgium
-are willing to sign a code of conduct referring to the inclusion/exclusion criteria, rules of the protocol and hygienic measures as well as travel restrictions.
-do not have any confirmed or suspected immunosuppressive or immunodeficiency condition, have been treated with immunosuppressant drugs or other immune-modifying drugs for longer than 14 days within 6 months prior to the first vaccine dose or have such use planned during the study.
-will not have household or professional contact with known immunosuppressed people or people without full polio vaccination during the whole study duration, or have professional contact with children under 6 months old during the whole study duration.
and excluded if:
-Any travel to polio endemic countries or countries with evidence of recent (within last 6 months) wild or vaccine-derived poliovirus circulation during the total duration of the study;
-Professional handling of food, catering activities (e.g. working in restaurant kitchen, bakery, ..) during the total duration of the study;

If type 2 virus shedding is detected by PCR on 1 of the 3 last stool samples study duration for this individual will be extended and subject asked to further collect 3 consecutive stool samples every 3 weeks after the last pp sample until shedding is PCR negative on 3 consecutive stool samples. Travel/other restrictions described above will continue to apply until end of shedding is reached. Additional risk assessment measure: household contact monitoring will be offered in case of extended shedding (PCR of at least 1 of the FU samples after D42 following last vaccination

Background therapy: -

Evidence for comparator:

Due to the withdrawal of Sabin mOPV2 and prohibition of its use from April 2016 onwards, well before the availability of nOPV2 for clinical testing, Phase 4 trials have been conducted with Sabin mOPV2 to provide control data on safety, immunogenicity, against which data for nOPV2 in subsequent Phase I and II studies will be evaluated and compared. The Phase 4 trials of Sabin mOPV2 were designed to parallel the expected design of the Phase 1 and 2 nOPV2 studies with respect to overall design, inclusion of similar study cohorts. The Phase 2 study is designed to evaluate the safety and immunogenicity of both nOPV2 vaccines in adults before testing in young children and then infants. The primary objectives

of the Phase 2 study include the general safety and immunogenicity of the two candidate vaccines, primarily based on comparison with historical data obtained in the Phase 4 study of Sabin mOPV2 for OPV-vaccinated subjects, in order to establish non-inferior immunogenicity and acceptable safety profile. Assessment of the general safety of the 2 candidate vaccines in IPV-only vaccinated subjects will be based on comparison with data from a placebo group.

Actual start date of recruitment	01 September 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 250
Worldwide total number of subjects	250
EEA total number of subjects	250

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)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	250
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted at 2 centers in Belgium. 277 volunteers were screened between Oct2018, and Feb2019, and 250 participants were enrolled. Eligible participants were healthy adults aged 18–50 years with documented history of at least 3 polio vaccinations with either oral polio vaccine (OPV) or inactivated polio vaccine (IPV)

Pre-assignment

Screening details:

nOPV2-c2 was prioritized so first 100 OPV-vaccinated adults were randomized 1:1 to Groups 3 and 4 to receive nOPV2-c2. Next 100 OPV-vaccinated adults were
randomized 1:1 to Groups 1 and 2 to receive nOPV2-c1. Parallel randomization of IPV-vaccinated adults: 2:1 to Group 6 or 7 until Group 6 was complete, then 2:1 randomization for Groups 5 +7

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Assessor

Blinding implementation details:

All OPV-vaccinated subjects will receive one of the nOPV2 candidates in a single blind manner and all IPV- vaccinated subjects will receive one of the nOPV2 candidates or placebo in a double-blinded manner.
For the whole study duration all subjects and blinded study staff responsible for safety evaluation of IPV- subjects will not have any information of what has been administered. As the placebo can be distinguished from the vaccine candidates in packaging and color, reception of the vaccines,

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1: OPV-vaccinated - One dose of Novel OPV2 Candidate 1

Arm description:

Participants previously vaccinated with oral polio vaccine (OPV) received one dose of novel OPV2 candidate 1 on Day 0, administered orally as six drops (0.3 mL total)

Arm type	Experimental
Investigational medicinal product name	nOPV2 candidate 1 (S2/cre5/S15domV/rec1/hifi3)
Investigational medicinal product code	nOPV2 candidate1
Other name	
Pharmaceutical forms	Oral drops
Routes of administration	Oral use

Dosage and administration details:

Participants previously vaccinated with OPV received one dose of novel oral polio vaccine type 2 (nOPV2)candidate 1 on study Day 0, administered orally as six drops (0.3 mL total).

Arm title	Group 2: OPV-vaccinated - Two doses of Novel OPV2 Candidate 1

Arm description:

Participants previously vaccinated with oral polio vaccine (OPV) received two doses of novel OPV2 candidate 1, 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL total)

Arm type	Experimental
Investigational medicinal product name	nOPV2 candidate 1 (S2/cre5/S15domV/rec1/hifi3)
Investigational medicinal product code	nOPV2 candidate1
Other name	
Pharmaceutical forms	Oral drops
Routes of administration	Oral use

Dosage and administration details:

Participants previously vaccinated with OPV received two doses of novel OPV2 candidate 1 28 days apart (Day
0 and Day 28), administered orally as six drops (0.3 mL total).

Arm title	Group 3: OPV-vaccinated - One dose of Novel OPV2 Candidate 2

Arm description:

Participants previously vaccinated with OPV received one dose of novel OPV2 candidate 2 on study Day 0, administered orally as six drops (0.3 mL total).

Arm type	Experimental
Investigational medicinal product name	nOPV2 candidate 2 (S2/S15domV/CpG40)
Investigational medicinal product code	nOPV2 candidate 2
Other name	
Pharmaceutical forms	Oral drops
Routes of administration	Oral use

Dosage and administration details:

Participants previously vaccinated with OPV received one dose of novel OPV2 candidate 2 on study Day 0,
administered orally as six drops (0.3 mL total; approximately 10# CCID50).

Arm title	Group 4: OPV-vaccinated - Two doses of Novel OPV2 Candidate 2

Arm description:

Participants previously vaccinated OPV received two doses novel OPV2 candidate 2 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL)

Arm type	Experimental
Investigational medicinal product name	nOPV2 candidate 2 (S2/S15domV/CpG40)
Investigational medicinal product code	nOPV2 candidate 2
Other name	
Pharmaceutical forms	Oral drops
Routes of administration	Oral use

Dosage and administration details:

Participants previously vaccinated with OPV received two doses of novel OPV2 candidate 2 28 days apart (Day
0 and Day 28), administered orally as six drops (0.3 mL total; approximately 10# CCID50).

Arm title	Group 5: IPV-vaccinated - Two doses of Novel OPV2 Candidate 1

Arm description:

Participants previously vaccinated with inactivated polio vaccine (IPV) received two doses of novel OPV2 candidate 1 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL).

Arm type	Experimental
Investigational medicinal product name	nOPV2 candidate 1 (S2/cre5/S15domV/rec1/hifi3)
Investigational medicinal product code	nOPV2 candidate1
Other name	
Pharmaceutical forms	Oral drops
Routes of administration	Oral use

Dosage and administration details:

Participants previously vaccinated with only IPV received two doses of novel OPV2 candidate 1 28 days apart
(Day 0 and Day 28), administered orally as six drops (0.3 mL).

Arm title	Group 6: IPV-vaccinated - Two doses of Novel OPV2 Candidate 2

Arm description:

Participants previously vaccinated with IPV received two doses of novel OPV2 candidate 2 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL total; approximately 10# CCID50)

Arm type	Experimental

Investigational medicinal product name	nOPV2 candidate 2 (S2/S15domV/CpG40)
Investigational medicinal product code	nOPV2 candidate 2
Other name	
Pharmaceutical forms	Oral drops
Routes of administration	Oral use

Dosage and administration details:

Participants previously vaccinated with only IPV received two doses of novel OPV2 candidate 2 28 days apart
(Day 0 and Day 28), administered orally as six drops (0.3 mL).

Arm title	Group 7: IPV-vaccinated - Two doses of placebo

Arm description:

Participants previously vaccinated with IPV received two doses of placebo 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL total)

Arm type	Placebo
Investigational medicinal product name	Sirupus Simplex, Propylenglycolum, Ph.Eur.
Investigational medicinal product code	Placebo
Other name	
Pharmaceutical forms	Oral drops
Routes of administration	Oral use

Dosage and administration details:

Participants previously vaccinated with only IPV received two doses of placebo 28 days apart (Day 0 and Day
28), administered orally as six drops.

Number of subjects in period 1	Group 1: OPV-vaccinated - One dose of Novel OPV2 Candidate 1	Group 2: OPV-vaccinated - Two doses of Novel OPV2 Candidate 1	Group 3: OPV-vaccinated - One dose of Novel OPV2 Candidate 2
Started	50	50	50
Completed	50	50	50

Number of subjects in period 1	Group 4: OPV-vaccinated - Two doses of Novel OPV2 Candidate 2	Group 5: IPV-vaccinated - Two doses of Novel OPV2 Candidate 1	Group 6: IPV-vaccinated - Two doses of Novel OPV2 Candidate 2
Started	50	17	16
Completed	50	17	16

Number of subjects in period 1	Group 7: IPV-vaccinated - Two doses of placebo
Started	17
Completed	17

Baseline characteristics

Reporting groups	
Reporting group title	Group 1: OPV-vaccinated - One dose of Novel OPV2 Candidate 1
Reporting group description:	
Participants previously vaccinated with oral polio vaccine (OPV) received one dose of novel OPV2 candidate 1 on Day 0, administered orally as six drops (0.3 mL total)	
Reporting group title	Group 2: OPV-vaccinated - Two doses of Novel OPV2 Candidate 1
Reporting group description:	
Participants previously vaccinated with oral polio vaccine (OPV) received two doses of novel OPV2 candidate 1, 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL total)	
Reporting group title	Group 3: OPV-vaccinated - One dose of Novel OPV2 Candidate 2
Reporting group description:	
Participants previously vaccinated with OPV received one dose of novel OPV2 candidate 2 on study Day 0, administered orally as six drops (0.3 mL total).	
Reporting group title	Group 4: OPV-vaccinated - Two doses of Novel OPV2 Candidate 2
Reporting group description:	
Participants previously vaccinated OPV received two doses novel OPV2 candidate 2 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL)	
Reporting group title	Group 5: IPV-vaccinated - Two doses of Novel OPV2 Candidate 1
Reporting group description:	
Participants previously vaccinated with inactivated polio vaccine (IPV) received two doses of novel OPV2 candidate 1 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL).	
Reporting group title	Group 6: IPV-vaccinated - Two doses of Novel OPV2 Candidate 2
Reporting group description:	
Participants previously vaccinated with IPV received two doses of novel OPV2 candidate 2 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL total; approximately 10# CCID50)	
Reporting group title	Group 7: IPV-vaccinated - Two doses of placebo
Reporting group description:	
Participants previously vaccinated with IPV received two doses of placebo 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL total)	

Reporting group values	Group 1: OPV-vaccinated - One dose of Novel OPV2 Candidate 1	Group 2: OPV-vaccinated - Two doses of Novel OPV2 Candidate 1	Group 3: OPV-vaccinated - One dose of Novel OPV2 Candidate 2
Number of subjects	50	50	50
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			

85 years and over			

Age continuous			
Units: years			
arithmetic mean	31	31	32
standard deviation	± 10	± 10	± 10
Gender categorical			
Units: Subjects			
Female	22	29	28
Male	28	21	22
Race/Ethnicity, Customized			
Units: Subjects			
White	49	49	49
Asian	0	0	1
Black or African American	0	0	0
other	1	1	0
Number of prior OPV vaccinations			
Units: Subjects			
None	0	0	0
Three	49	50	41
Four	1	0	9
Five	0	0	0
Number of prior IPV vaccinations			
Units: Subjects			
None	46	49	48
One	4	1	2
Four	0	0	0
Five	0	0	0
Six or more	0	0	0

Reporting group values	Group 4: OPV-vaccinated - Two doses of Novel OPV2 Candidate 2	Group 5: IPV-vaccinated - Two doses of Novel OPV2 Candidate 1	Group 6: IPV-vaccinated - Two doses of Novel OPV2 Candidate 2
Number of subjects	50	17	16
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: years			
arithmetic mean	34	23	31
standard deviation	± 10	± 10	± 9

Gender categorical Units: Subjects			
Female	32	11	13
Male	18	6	3
Race/Ethnicity, Customized Units: Subjects			
White	49	16	16
Asian	0	0	0
Black or African American	0	0	0
other	1	1	0
Number of prior OPV vaccinations Units: Subjects			
None	0	17	16
Three	40	0	0
Four	9	0	0
Five	1	0	0
Number of prior IPV vaccinations Units: Subjects			
None	47	0	0
One	3	0	0
Four	0	6	4
Five	0	10	5
Six or more	0	1	7

Reporting group values	Group 7: IPV-vaccinated - Two doses of placebo	Total	
Number of subjects	17	250	
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	24		
standard deviation	± 9	-	
Gender categorical Units: Subjects			
Female	14	149	
Male	3	101	
Race/Ethnicity, Customized Units: Subjects			
White	15	243	
Asian	0	1	

Black or African American	1	1	
other	1	5	
Number of prior OPV vaccinations Units: Subjects			
None	17	50	
Three	0	180	
Four	0	19	
Five	0	1	
Number of prior IPV vaccinations Units: Subjects			
None	0	190	
One	0	10	
Four	10	20	
Five	5	20	
Six or more	2	10	

End points

End points reporting groups

Reporting group title	Group 1: OPV-vaccinated - One dose of Novel OPV2 Candidate 1
Reporting group description:	
Participants previously vaccinated with oral polio vaccine (OPV) received one dose of novel OPV2 candidate 1 on Day 0, administered orally as six drops (0.3 mL total)	
Reporting group title	Group 2: OPV-vaccinated - Two doses of Novel OPV2 Candidate 1
Reporting group description:	
Participants previously vaccinated with oral polio vaccine (OPV) received two doses of novel OPV2 candidate 1, 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL total)	
Reporting group title	Group 3: OPV-vaccinated - One dose of Novel OPV2 Candidate 2
Reporting group description:	
Participants previously vaccinated with OPV received one dose of novel OPV2 candidate 2 on study Day 0, administered orally as six drops (0.3 mL total).	
Reporting group title	Group 4: OPV-vaccinated - Two doses of Novel OPV2 Candidate 2
Reporting group description:	
Participants previously vaccinated OPV received two doses novel OPV2 candidate 2 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL)	
Reporting group title	Group 5: IPV-vaccinated - Two doses of Novel OPV2 Candidate 1
Reporting group description:	
Participants previously vaccinated with inactivated polio vaccine (IPV) received two doses of novel OPV2 candidate 1 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL).	
Reporting group title	Group 6: IPV-vaccinated - Two doses of Novel OPV2 Candidate 2
Reporting group description:	
Participants previously vaccinated with IPV received two doses of novel OPV2 candidate 2 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL total; approximately 10# CCID50)	
Reporting group title	Group 7: IPV-vaccinated - Two doses of placebo
Reporting group description:	
Participants previously vaccinated with IPV received two doses of placebo 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL total)	
Subject analysis set title	Group 1+2: OPV-vaccinated - novel OPV2 candidate 1
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants previously vaccinated with OPV received vaccination with novel OPV2 candidate 1 on study Day 0.	
Subject analysis set title	Group 3+4: OPV-vaccinated - novel OPV2 candidate 2
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants previously vaccinated with OPV received vaccination with novel OPV2 candidate 2 on study Day 0	
Subject analysis set title	Group 2: OPV-vaccinated - novel OPV2 candidate 1 Post-dose 2
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants previously vaccinated with OPV received a second vaccination with novel OPV2 candidate 1 on Day 28.	
Subject analysis set title	Group 4: OPV-vaccinated - novel OPV2 Candidate 2 Post-dose 2
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants previously vaccinated with OPV received a second vaccination with novel OPV2 candidate 2 on
Day 28.

Subject analysis set title	Group 5: IPV-vaccinated - Novel OPV2 Candidate 1 Post-dose 1
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants previously vaccinated with only IPV received a vaccination with novel OPV2 candidate 1 on Day 0.

Subject analysis set title	Group 5: IPV-vaccinated - Novel OPV2 Candidate 1 Post-dose 2
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants previously vaccinated with only IPV received a second vaccination with novel OPV2 candidate 1 on
Day 28.

Subject analysis set title	Group 6: IPV-vaccinated - novel OPV candidate 2 Post-dose 1
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants previously vaccinated with only IPV received a vaccination with novel OPV2 candidate 2 on Day 0.

Subject analysis set title	Group 6: IPV-vaccinated - novel OPV candidate 2 Post-dose 2
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants previously vaccinated with only IPV received a second vaccination with novel OPV2 candidate 2 on
Day 28.

Subject analysis set title	Group 7: IPV-vaccinated - Placebo Post-dose 1
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants previously vaccinated with only IPV received a vaccination with placebo on Day 0.

Subject analysis set title	Group 7: IPV-vaccinated - Placebo Post-dose 2
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants previously vaccinated with only IPV received a second vaccination with placebo on Day 28.

Subject analysis set title	Group 1+2: OPV-vaccinated - Novel OPV2 candidate 1 Post-dose 1
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants previously vaccinated with OPV received vaccination with novel OPV2 candidate 1 on study Day 0.

Subject analysis set title	Group 3+4: OPV-vaccinated - novel OPV2 candidate 2 Post-dose 1
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants previously vaccinated with OPV received vaccination with novel OPV2 candidate 2 on study Day 0.

Subject analysis set title	Group 5: IPV-vaccinated - Novel OPV2 Candidate 1
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants previously vaccinated with only IPV received a vaccination with novel OPV2 candidate 1 on Day 0.

Subject analysis set title	Group 6: IPV-vaccinated - Novel OPV2 Candidate 2
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants previously vaccinated with only IPV received a vaccination with novel OPV2 candidate 2 on Day 0.

Subject analysis set title	Group 7: IPV-vaccinated - Placebo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants previously vaccinated with only IPV received a vaccination with placebo on Day 0.

Primary: Number of Participants With Serious Adverse Events (SAEs) and Severe Adverse Events

End point title	Number of Participants With Serious Adverse Events (SAEs) and Severe Adverse Events

End point description:

An SAE is any untoward medical occurrence that at any dose met any of the following conditions:
• Resulted in death;
• Was life-threatening;
• Required inpatient hospitalization or prolongation of existing inpatient hospitalization;
• Resulted in persistent or significant disability/incapacity;
• Was a congenital anomaly/birth defect;
• Was medically important.
A solicited AE is a pre-selected sign or symptom that occurred within 7 days after each dose, whereas unsolicited
AEs were collected throughout the study. Solicited AEs included headache, fatigue, myalgia, arthralgia, paresthesia,
anesthesia, paralysis, nausea, vomiting, diarrhea, abdominal pain, and fever.
A severe AE is an AE that prevented normal everyday activities and which was not classified as an SAE.
A related AE is an AE the investigator considered probably or possibly caused by the study vaccine, meaning that there
was a reasonable temporal association or the AE was not attributable to other conditions.

End point type	Primary

End point timeframe:

Up to 42 days after each vaccination

End point values	Group 1: OPV-vaccinated - One dose of Novel OPV2 Candidate 1	Group 2: OPV-vaccinated - Two doses of Novel OPV2 Candidate 1	Group 3: OPV-vaccinated - One dose of Novel OPV2 Candidate 2	Group 4: OPV-vaccinated - Two doses of Novel OPV2 Candidate 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	50	50
Units: participants				
Serious or Severe adverse event	9	16	5	8
Serious adverse events	1	1	0	1
Serious solicited adverse events	0	0	0	0
Serious unsolicited adverse events	1	1	0	1
Serious adverse events related to study vaccine	0	0	0	0
Severe adverse events	9	16	5	8
Severe solicited adverse events	1	2	1	2
Severe unsolicited adverse events	8	15	4	7
Severe adverse events related to study vaccine	1	2	1	2

End point values	Group 5: IPV-vaccinated - Two doses of	Group 6: IPV-vaccinated - Two doses of	Group 7: IPV-vaccinated - Two doses of	

	Novel OPV2 Candidate 1	Novel OPV2 Candidate 2	placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	16	17	
Units: participants				
Serious or Severe adverse event	5	6	10	
Serious adverse events	0	1	0	
Serious solicited adverse events	0	0	0	
Serious unsolicited adverse events	0	1	0	
Serious adverse events related to study vaccine	0	1	0	
Severe adverse events	5	6	10	
Severe solicited adverse events	1	1	2	
Severe unsolicited adverse events	4	5	9	
Severe adverse events related to study vaccine	2	5	4	

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

The number of participants with severe solicited adverse events in the OPV-vaccinated groups who received nOPV-c1 (combined Groups 1 and 2) was compared with the corresponding endpoint from the historical monovalent OPV2 control study (UAM1, EudraCT # 2015-003325-33) using the two-sided Fisher's exact test. In the UAM1 study, the number of participants with severe solicited adverse events was 5 out of 100.

Comparison groups	Group 1: OPV-vaccinated - One dose of Novel OPV2 Candidate 1 v Group 2: OPV-vaccinated - Two doses of Novel OPV2 Candidate 1
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.7209
Method	Fisher exact

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

The number of participants with severe solicited adverse events in the OPV-vaccinated groups who received nOPV-c2 (combined Groups 3 and 4) was compared with the corresponding endpoint from the historical monovalent OPV2 control study (UAM1, EudraCT # 2015-003325-33) using the two-sided Fisher's exact test. In the UAM1 study, the number of participants with severe solicited adverse events was 5 out of 100.

Comparison groups	Group 3: OPV-vaccinated - One dose of Novel OPV2 Candidate 2 v Group 4: OPV-vaccinated - Two doses of Novel OPV2 Candidate 2

Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.7209
Method	Fisher exact

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

The number of participants with severe unsolicited adverse events in the OPV-vaccinated groups who received nOPV-c1 (combined Groups 1 and 2) was compared with the corresponding endpoint from the historical monovalent OPV2 control study (UAM1, EudraCT # 2015-003325-33) using the two-sided Fisher's exact test. In the UAM1 study, the number of participants with severe unsolicited adverse events was 17 out of 100.

Comparison groups	Group 1: OPV-vaccinated - One dose of Novel OPV2 Candidate 1 v Group 2: OPV-vaccinated - Two doses of Novel OPV2 Candidate 1
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.3769
Method	Fisher exact

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

The number of participants with severe unsolicited adverse events in the OPV-vaccinated groups who received nOPV-c2 (combined Groups 3 and 4) was compared with the corresponding endpoint from the historical monovalent OPV2 control study (UAM1, EudraCT # 2015-003325-33) using the two-sided Fisher's exact test. In the UAM1 study, the number of participants with severe unsolicited adverse events was 17 out of 100.

Comparison groups	Group 3: OPV-vaccinated - One dose of Novel OPV2 Candidate 2 v Group 4: OPV-vaccinated - Two doses of Novel OPV2 Candidate 2
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.3083
Method	Fisher exact

Statistical analysis title	Statistical Analysis 5

Statistical analysis description:

The number of participants with serious unsolicited adverse events in the OPV-vaccinated groups who received nOPV-c1 (combined Groups 1 and 2) was compared with the corresponding endpoint from the historical monovalent OPV2 control study (UAM1, EudraCT # 2015-003325-33) using the two-sided Fisher's exact test. In the UAM1 study, the number of participants with serious unsolicited adverse events was 0 out of 100.

Comparison groups	Group 1: OPV-vaccinated - One dose of Novel OPV2 Candidate 1 v Group 2: OPV-vaccinated - Two doses of Novel OPV2 Candidate 1

Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.4975
Method	Fisher exact

Statistical analysis title	Statistical Analysis 6

Statistical analysis description:

The number of participants with serious unsolicited adverse events in the OPV-vaccinated groups who received nOPV-c2 (combined Groups 3 and 4) was compared with the corresponding endpoint from the historical monovalent OPV2 control study (UAM1, EudraCT # 2015-003325-33) using the two-sided Fisher's exact test. In the UAM1 study, the number of participants with serious unsolicited adverse events was 0 out of 100.

Comparison groups	Group 3: OPV-vaccinated - One dose of Novel OPV2 Candidate 2 v Group 4: OPV-vaccinated - Two doses of Novel OPV2 Candidate 2
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	other
P-value	= 1
Method	Fisher exact

Statistical analysis title	Statistical Analysis 7

Statistical analysis description:

comparison of severe solicited adverse events

Comparison groups	Group 5: IPV-vaccinated - Two doses of Novel OPV2 Candidate 1 v Group 7: IPV-vaccinated - Two doses of placebo
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	other
P-value	= 1
Method	Fisher exact

Statistical analysis title	Statistical Analysis 8

Statistical analysis description:

comparison of severe solicited adverse events

Comparison groups	Group 6: IPV-vaccinated - Two doses of Novel OPV2 Candidate 2 v Group 7: IPV-vaccinated - Two doses of placebo
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	other
P-value	= 1
Method	Fisher exact

Statistical analysis title	Statistical Analysis 9
Statistical analysis description: comparison of severe unsolicited adverse events	
Comparison groups	Group 5: IPV-vaccinated - Two doses of Novel OPV2 Candidate 1 v Group 7: IPV-vaccinated - Two doses of placebo
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.1571
Method	Fisher exact

Statistical analysis title	Statistical Analysis 10
Statistical analysis description: comparison of severe unsolicited adverse events	
Comparison groups	Group 6: IPV-vaccinated - Two doses of Novel OPV2 Candidate 2 v Group 7: IPV-vaccinated - Two doses of placebo
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.296
Method	Fisher exact

Primary: Seroprotection Rate After a Single Dose of Novel OPV2 in Former OPV Recipients

End point title	Seroprotection Rate After a Single Dose of Novel OPV2 in Former OPV Recipients

End point description:

Measure Description:
Seroprotection rate was defined as the percentage of participants with anti-type 2-specific poliovirus neutralizing antibody titers ≥ 1:8.
Neutralizing antibodies against poliovirus type 2 were determined using the World Health Organization (WHO) standard microneutralization assay (WHO EPI GEN 93.9). The lower limit of quantitation (LLOQ) was 5.7 and the upper limit of quantitation (ULOQ) was 1448.
Analysis Population Description:
Participants in the per-protocol population previously vaccinated with OPV. The per-protocol population excluded participants with missed doses or major
protocol deviations considered to have a potential impact on immunogenicity from the time of the deviation and at all time points thereafter.
This endpoint was analyzed after one dose of nOPV hence Groups 1 and 2 and Groups 3 and 4 are combined for analysis, as specified in the study protocol.

End point type	Primary

End point timeframe:

Baseline (Day 0 prior to vaccination) and Day 28

End point values	Group 1+2: OPV-vaccinated - novel OPV2 candidate 1	Group 3+4: OPV-vaccinated - novel OPV2 candidate 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	98	98		
Units: percentage or participants				
number (confidence interval 95%)				
Day 0 (pre-vaccination) Day 28	99 (94 to 100) 100 (96 to 100)	94 (87 to 98) 100 (96 to 100)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

The seroprotection rate after 1 dose of eithervaccine candidate in the OPV-vaccinated groups (nOPV2 combined groups 1 and 2,and combined groups 3 and 4), was compared with the corresponding endpoint from the historical monovalent OPV2 (mOPV2) control study (UAM1, EudraCT # 2015-003325-33). In the UAM1 study, the observed seroprotection rate after 1 dose of mOPV2 was98% (98 out of 100 participants), with 95% confidence interval (CI) of 93-100%.
Stat. Analysis 1 regards only comparison Group 1+2

Comparison groups	Group 1+2: OPV-vaccinated - novel OPV2 candidate 1 v Group 3+4: OPV-vaccinated - novel OPV2 candidate 2
Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Parameter estimate	Difference
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	7

Notes:

[1] - The primary immunogenicity endpoint, seroprotection on Day 28 after a single dose of each vaccine candidate, was formally compared with the corresponding endpoint from UAM1 via a non-inferiority test of the difference of each of the novel candidates to the monovalent OPV2 control, mOPV2, each using one-sided α=0.025 and a non-inferiority margin of 10%, computed using two-sided α=0·05 Miettinen and Nurminen score-based CIs for inference.

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

The seroprotection rate after 1 dose of either vaccine candidate in the OPV-vaccinated groups (nOPV2 combined groups 1 and 2, and combined groups 3 and 4), was compared with the corresponding endpoint from the historical monovalent OPV2 control study (UAM1, EudraCT # 2015-003325-33). In the UAM1 study, the observed seroprotection rate after 1 dose of mOPV2 was 98% (98 out of 100 participants), with a 95% confidence interval (CI) of 93-100%.
Stat. Analysis 2 regards only comparison Group 3+4

Comparison groups	Group 3+4: OPV-vaccinated - novel OPV2 candidate 2 v Group 1+2: OPV-vaccinated - novel OPV2 candidate 1

Number of subjects included in analysis	196
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Parameter estimate	Difference
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	7

Notes:

[2] - The primary immunogenicity endpoint, seroprotection on Day 28 after a single dose of each vaccine candidate, was formally compared with the corresponding endpoint from UAM1 via a non-inferiority test of the difference of each of the novel candidates to the monovalent OPV2 control, mOPV2, each using one-sided α=0.025 and a non-inferiority margin of 10%, computed using two-sided α=0·05 Miettinen and Nurminen score-based CIs for inference.

Secondary: Number of Former OPV Recipients With Solicited Adverse Events Within 7 Days of Vaccination With Novel OPV2

End point title	Number of Former OPV Recipients With Solicited Adverse Events Within 7 Days of Vaccination With Novel OPV2

End point description:

Measure description:
Subjects completed 7-day diary cards soliciting systemic AEs and daily oral temperature.
Solicited AEs: selected signs and symptoms including headache, fatigue, myalgia, arthralgia, paresthesia, anesthesia, paralysis, nausea, vomiting, diarrhea and abdominal pain, or fever defined as temperature ≥37.5°C. AEs were graded as mild (easily tolerated with minimal discomfort or temperature 37.5°C to 38.0°C), moderate (sufficiently discomforting to interfere with normal everyday activities, or temp. 38.1°C to 39.0°C), or severe (preventing normal everyday activities, or temperatures > 39.0°C). AEs were assessed by the investigator for causality. Probably related suggests that a reasonable temporal sequence of the AE with vaccine administration exists and, in the Investigator's clinical judgment, it is likely that a causal relationship exists between the vaccine administration and the AE
Population description: OPV-vaccinated subjects in total vaccinated population

End point type	Secondary

End point timeframe:

Up to 7 days after each dose (Day 0-7 post-dose 1 and Day 28-35 post-dose 2)

End point values	Group 2: OPV-vaccinated - novel OPV2 candidate 1 Post-dose 2	Group 4: OPV-vaccinated - novel OPV2 Candidate 2 Post-dose 2	Group 1+2: OPV-vaccinated - Novel OPV2 candidate 1 Post-dose 1	Group 3+4: OPV-vaccinated - novel OPV2 candidate 2 Post-dose 1
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	49	100	49
Units: subjects				
Any solicited adverse event	71	26	74	21
Mild	45	18	60	14
Moderate	23	8	12	6
Severe	3	0	2	1
Probably related to vaccination	44	15	37	12

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Former IPV Recipients With Solicited Adverse Events After Vaccination With Novel OPV2

End point title	Number of Former IPV Recipients With Solicited Adverse Events After Vaccination With Novel OPV2

End point description:

Measure description:Subjects completed 7-day diary cards soliciting systemic AEs and daily oral temperature. Solicited AEs comprised selected signs and symptoms including headache, fatigue, myalgia, arthralgia, paresthesia, anesthesia, paralysis, nausea, vomiting, diarrhea and abdominal pain, or fever defined as a temperature ≥37.5°C. AEs were graded as mild (easily tolerated with minimal discomfort or temperature 37.5°C to 38.0°C), moderate (sufficiently discomforting to interfere with normal everyday activities, or temp. 38.1°C to 39.0°C), or severe (preventing normal everyday activities, or temperatures > 39.0°C). AEs were assessed by the investigator for causality. Probably related suggests that a reasonable temporal sequence of the AE with vaccine administration exists and, in the Investigator's clinical judgment, it is likely that a causal relationship exists between the vaccine administration and the AE,
Population: IPV-vaccinated subjects in the total vaccinated population

End point type	Secondary

End point timeframe:

7 days post-dose (Day 0-7 post-dose 1 and and Day 28-35 post-dose 2)

End point values	Group 5: IPV-vaccinated - Novel OPV2 Candidate 1 Post-dose 1	Group 5: IPV-vaccinated - Novel OPV2 Candidate 1 Post-dose 2	Group 6: IPV-vaccinated - novel OPV candidate 2 Post-dose 1	Group 6: IPV-vaccinated - novel OPV candidate 2 Post-dose 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	17	17	16	15
Units: subjects				
Any solicited adverse events	16	11	13	9
Mild	11	8	6	3
Moderate	4	3	7	5
Severe	1	0	0	1
Probably related to vaccination	9	8	5	8

End point values	Group 7: IPV-vaccinated - Placebo Post-dose 1	Group 7: IPV-vaccinated - Placebo Post-dose 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	17	16		
Units: subjects				

Any solicited adverse events	15	12		
Mild	9	7		
Moderate	4	5		
Severe	2	0		
Probably related to vaccination	9	5		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Unsolicited Adverse Events

End point title	Number of Participants With Unsolicited Adverse Events

End point description:

Measure description:
Unsolicited events comprised other signs and symptoms that participants reported through the end of the study. Each
unsolicited AE was rated on a 3-point scale of increasing intensity:
• Grade 1: Mild; an AE that was easily tolerated by the subject, causing minimal discomfort and not interfering with
everyday activities.
• Grade 2: Moderate; an AE that was sufficiently discomforting to interfere with normal everyday activities.
• Grade 3: Severe; an AE that prevented normal everyday activities. Each adverse event was assessed by the
investigator for causality as unrelated, unlikely, possibly, or probably related to the vaccination.
Analysis Population Description:
Total vaccinated population

End point type	Secondary

End point timeframe:

Up to 42 days after each vaccination

End point values	Group 1: OPV-vaccinated - One dose of Novel OPV2 Candidate 1	Group 2: OPV-vaccinated - Two doses of Novel OPV2 Candidate 1	Group 3: OPV-vaccinated - One dose of Novel OPV2 Candidate 2	Group 4: OPV-vaccinated - Two doses of Novel OPV2 Candidate 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	50	50
Units: subjects				
Any unsolicited adverse event	34	43	38	42
Mild	8	10	10	11
Moderate	18	18	24	24
Severe	8	15	4	7
Probably related to vaccination	2	2	1	2

End point values	Group 5: IPV-vaccinated - Two doses of Novel OPV2	Group 6: IPV-vaccinated - Two doses of Novel OPV2	Group 7: IPV-vaccinated - Two doses of placebo	

	Candidate 1	Candidate 2		
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	16	17	
Units: subjects				
Any unsolicited adverse event	15	13	17	
Mild	3	0	1	
Moderate	8	8	7	
Severe	4	5	9	
Probably related to vaccination	1	2	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Former OPV Recipients With Clinically Relevant Laboratory Abnormalities Up to 28 Days After Each Vaccination

End point title	Number of Former OPV Recipients With Clinically Relevant Laboratory Abnormalities Up to 28 Days After Each Vaccination[3]

End point description:

Measure Description:
Laboratory assessments were collected at one-week intervals from Day 0 to Day 28 (except for Day 21) and at Days
35, 42, and 56 for participants in Groups 2 and 4 who received a 2nd dose.
The Investigator reviewed laboratory values outside the normal range and assessed their clinical relevance.
Any clinically relevant abnormal lab values that occurred at any visit up to 28 days after the first vaccination (in
combined Groups 1 and 2 and Groups 3 and 4) and up to 28 days (Day 56) after the second dose (Groups 2 and 4) are
reported.
Analysis Population Description:
Participants in the total vaccinated population previously vaccinated with OPV.

End point type	Secondary

End point timeframe:

Day 0, Day 7, Day 14, and Day 28 for Groups 1-4 and at Day 35, Day 42, and Day 56 for participants in Groups 2 and 4

Notes:

[3] - 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: The endpoint for the other arms is defined as a separate endpoint in the protocol and therefore also separated reported in the endpoint: Number of Former IPV Recipients with Clinically Relevant Laboratory Abnormalities Up to 28 Days After Each Vaccination

End point values	Group 2: OPV-vaccinated - Two doses of Novel OPV2 Candidate 1	Group 4: OPV-vaccinated - Two doses of Novel OPV2 Candidate 2	Group 1+2: OPV-vaccinated - Novel OPV2 candidate 1 Post-dose 1	Group 3+4: OPV-vaccinated - novel OPV2 candidate 2 Post-dose 1
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	50	50		
Units: subjects	18	15	28	30

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Former IPV Recipients With Clinically Relevant Laboratory Abnormalities Up to 28 Days After Each Vaccination

End point title	Number of Former IPV Recipients With Clinically Relevant Laboratory Abnormalities Up to 28 Days After Each Vaccination[4]

End point description:

Measure Description
Laboratory assessments were collected at one-week intervals from Day 0 to Day 56, except for Days 21 and 49. The
Investigator reviewed laboratory values outside the normal range and assessed their clinical relevance. Any clinically relevant abnormal laboratory abnormalities that occurred at any visit up to 56 days are reported.
Analysis Population Description:
Participants in the total vaccinated population previously vaccinated with IPV only.

End point type	Secondary

End point timeframe:

Day 0, Day 7, Day 14, Day 28, Day 35, Day 42 and Day 56

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: The endpoint for the other arms is defined as a separate endpoint in the protocol and therefore also separated reported in the endpoint: Number of Former OPV Recipients with Clinically Relevant Laboratory Abnormalities Up to 28 Days After Each Vaccination

End point values	Group 5: IPV-vaccinated - Two doses of Novel OPV2 Candidate 1	Group 6: IPV-vaccinated - Two doses of Novel OPV2 Candidate 2	Group 7: IPV-vaccinated - Two doses of placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	16	17	
Units: subjects	4	6	9	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-Poliovirus Type-2 Neutralizing Antibody Titers After A Single Dose of Novel OPV2

End point title	Anti-Poliovirus Type-2 Neutralizing Antibody Titers After A Single Dose of Novel OPV2

End point description:

Measure Description:
Neutralizing antibodies against poliovirus type 2 were determined using the World Health Organization (WHO) standard
microneutralization assay (WHO EPI GEN 93.9). The lower limit of quantitation (LLOQ) was 5.7 and the upper limit
of quantitation (ULOQ) was 1448. Data were calculated on log2-transformed type 2 neutralizing titers and back
transformed for the presentation below. Values shown as 1448 should be interpreted as ≥ 1448.
Analysis Population Description:
Per-protocol population. The per-protocol population excluded participants with missed doses or major protocol deviations considered to have a potential
impact on immunogenicity from the time of the deviation and at all time points thereafter. This endpoint

was analyzed after one dose of nOPV hence Groups
1 and 2 and Groups 3 and 4 are combined for analysis, as specified in the study protocol. Samples for 2 participants in Group 5 on Day 0 were mixed up and
are not included in the analysis.

End point type	Secondary

End point timeframe:

Day 0 and Day 28

End point values	Group 1+2: OPV-vaccinated - novel OPV2 candidate 1	Group 3+4: OPV-vaccinated - novel OPV2 candidate 2	Group 5: IPV-vaccinated - Novel OPV2 Candidate 1	Group 6: IPV-vaccinated - Novel OPV2 Candidate 2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	98	98	17	16
Units: titer				
median (inter-quartile range (Q1-Q3))				
Day 0 (pre-vaccination)	324 (228 to 455)	455 (256 to 724)	228 (74 to 588)	144 (26 to 446)
Day 28	1448 (1448 to 1448)	1152 (815 to 1448)	1448 (1448 to 1448)	1448 (1176 to 1448)

End point values	Group 7: IPV-vaccinated - Placebo			
Subject group type	Subject analysis set			
Number of subjects analysed	16			
Units: titer				
median (inter-quartile range (Q1-Q3))				
Day 0 (pre-vaccination)	91 (11 to 362)			
Day 28	51 (8 to 256)			

Statistical analyses

No statistical analyses for this end point

Secondary: Seroprotection Rate 28 Days After Two Doses of Novel OPV2 in Former OPV Recipients

End point title	Seroprotection Rate 28 Days After Two Doses of Novel OPV2 in Former OPV Recipients[5]

End point description:

Measure Description:
Seroprotection rate was defined as the percentage of participants with anti-type 2-specific poliovirus neutralizing
antibodies titers ≥ 1:8.

Analysis Population Description:
Participants in the per-protocol population previously vaccinated with OPV who received 2 doses of novel OPV2 (Groups 2 and 4).

End point type	Secondary

End point timeframe:

Day 56

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: The endpoint for the other arms is defined as a separate endpoint in the protocol and therefore also separated reported in the endpoint: Seroprotection Rate in Former IPV Recipients.

End point values	Group 2: OPV-vaccinated - Two doses of Novel OPV2 Candidate 1	Group 4: OPV-vaccinated - Two doses of Novel OPV2 Candidate 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	49		
Units: percentage of participants				
number (confidence interval 95%)	100 (93 to 100)	100 (93 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Seroprotection Rate in Former IPV Recipients

End point title	Seroprotection Rate in Former IPV Recipients[6]

End point description:

Measure Description:
Seroprotection rate was defined as the percentage of participants with anti-type 2-specific poliovirus neutralizing
antibodies titers ≥ 1:8.

Analysis Population Description
Participants in the per-protocol population previously vaccinated with IPV only. Samples for 2 participants in Group 5 on Day 0 were mixed up and are not
included in the analysis

End point type	Secondary

End point timeframe:

Day 0, Day 28, and Day 56

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: The endpoint for the other arms is defined as a separate endpoint in the protocol and therefore also separated reported in the endpoint: Seroprotection Rate After Two Doses of Novel OPV2 in Former OPV Recipients.

End point values	Group 5: IPV-vaccinated - Two doses of Novel OPV2 Candidate 1	Group 6: IPV-vaccinated - Two doses of Novel OPV2 Candidate 2	Group 7: IPV-vaccinated - Two doses of placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	16	16	
Units: percentage of participants				
number (confidence interval 95%)				
Day 0 (pre-vaccination)	93 (68 to 100)	94 (70 to 100)	81 (54 to 96)	

Day 28	100 (80 to 100)	100 (79 to 100)	75 (48 to 93)	
Day 56	100 (80 to 100)	100 (78 to 100)	81 (54 to 96)	

Statistical analyses

No statistical analyses for this end point

Secondary: Seroconversion Rate After a Single Dose of Novel OPV2 in Former OPV Recipients

End point title	Seroconversion Rate After a Single Dose of Novel OPV2 in Former OPV Recipients

End point description:

measure descripyion:
Seroconversion is defined as a change from seronegative to seropositive (poliovirus type-2-specific neutralizing
antibody titers ≥ 1:8), or for participants seropositive at Baseline, an antibody titer increase of ≥ 4-fold over Baseline
titer.
Analysis Population Description:
Participants in the seroconversion subset of the per-protocol population previously vaccinated with OPV. The seroconversion subset included participants
with Baseline titer sufficiently low to enable observation of a four-fold increase without breaching the ULOQ (ie, a titer ≤ 362).
Since this endpoint was analyzed after 1 dose of nOPV, Groups 1 and 2 and Groups 3 and 4 are combined for analysis.

End point type	Secondary

End point timeframe:

Day 28

End point values	Group 1+2: OPV-vaccinated - novel OPV2 candidate 1	Group 3+4: OPV-vaccinated - novel OPV2 candidate 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	55	47		
Units: percentage of participants				
number (confidence interval 95%)	74.5 (61.0 to 85.3)	51.1 (36.1 to 65.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Seroconversion Rate After Two Doses of Novel OPV2 in Former OPV Recipients

End point title	Seroconversion Rate After Two Doses of Novel OPV2 in Former OPV Recipients[7]

End point description:

Measure description:
Seroconversion is defined as a change from seronegative to seropositive (poliovirus type-2-specific neutralizing
antibody titers ≥ 1:8), or for participants seropositive at Baseline, an antibody titer increase of ≥ 4-fold over Baseline
titer.
Analysis Population Description:
Participants in the seroconversion subset of the per-protocol population previously vaccinated with OPV and who received 2 doses of novel OPV2 (Groups 2
and 4). The seroconversion subset included participants with Baseline titer sufficiently low to enable observation of a four-fold increase without breaching the
ULOQ (ie, a titer ≤ 362).

End point type	Secondary

End point timeframe:

Day 56

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: The endpoint for the other arms is defined as a separate endpoint in the protocol and therefore also separated reported in the endpoint: Seroconversion Rate After Two Doses of Novel OPV2 in Former OPV Recipients.

End point values	Group 2: OPV-vaccinated - Two doses of Novel OPV2 Candidate 1	Group 4: OPV-vaccinated - Two doses of Novel OPV2 Candidate 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	26		
Units: percentage of participants				
number (confidence interval 95%)	74 (54 to 89)	58 (37 to 77)		

Statistical analyses

No statistical analyses for this end point

Secondary: Seroconversion Rate in Former IPV Recipients

End point title	Seroconversion Rate in Former IPV Recipients[8]

End point description:

Measure description:
Seroconversion is defined as a change from seronegative to seropositive (poliovirus type-2-specific neutralizing
antibody titers ≥ 1:8), or for participants seropositive at Baseline, a poliovirus type-2-specific neutralizing antibody titer
increase of ≥ 4-fold over Baseline titer.

Analysis Population Description
Participants in the seroconversion subset of the per-protocol population previously vaccinated with IPV only. The seroconversion subset included participants
with Baseline titer sufficiently low to enable observation of a four-fold increase without breaching the ULOQ (ie, a titer ≤ 362).

End point type	Secondary

End point timeframe:

Day 28 and Day 56

Notes:

[8] - 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: The endpoint for the other arms is defined as a separate endpoint in the protocol and therefore also separated reported in the endpoint: Seroconversion Rate After Two Doses of Novel OPV2 in Former OPV Recipients.

End point values	Group 5: IPV-vaccinated - Two doses of Novel OPV2 Candidate 1	Group 6: IPV-vaccinated - Two doses of Novel OPV2 Candidate 2	Group 7: IPV-vaccinated - Two doses of placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	12	12	
Units: percentage of participants				
number (confidence interval 95%)				
Day 28	100 (69 to 100)	92 (62 to 100)	0 (0 to 26)	
Day 56	100 (69 to 100)	82 (48 to 98)	8 (0 to 38)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 42 days after each vaccination (42 days in Groups 1 and 3 and 70 days for all other Groups).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	Group1: OPV-vaccinated - One dose of Novel OPV2 candidate 1

Reporting group description:

Group1: OPV-vaccinated - One dose of Novel OPV2 candidate 1

Reporting group title	Group 2: OPV-vaccinated - two doses of novel OPV2 candidate 1

Reporting group description:

Participants previously vaccinated with oral polio vaccine (OPV) received two doses of novel OPV2 candidate 1, 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL total; approximately 10# 50% CCID50).

Reporting group title	Group 3: OPV-vaccinated - One dose of novel OPV2 candidate 2

Reporting group description:

Participants previously vaccinated with OPV received one dose of novel OPV2 candidate 2 on study Day 0, administered orally as six drops (0.3 mL total; approximately 10# CCID50).

Reporting group title	Group 4: OPV-vaccinated - Two doses of novel OPV2 candidate 2

Reporting group description:

Participants previously vaccinated OPV received two doses novel OPV2 candidate 2 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL total; approximately 10# CCID50).

Reporting group title	Group 5: IPV-vaccinated - Two doses of novel OPV2 candidate 1

Reporting group description:

Participants previously vaccinated with inactivated polio vaccine (IPV) received two doses of novel OPV2 candidate 1 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL total; approximately 10# CCID50).

Reporting group title	Group 6: IPV-vaccinated - Two doses of novel OPV2 candidate 2

Reporting group description:

Participants previously vaccinated with IPV received two doses of novel OPV2 candidate 2 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL total; approximately 10# CCID50).

Reporting group title	Group 7: IPV-vaccinated - Two doses of placebo

Reporting group description:

Participants previously vaccinated with IPV received two doses of placebo 28 days apart (Day 0 and Day 28), administered orally as six drops (0.3 mL total).

Serious adverse events	Group1: OPV-vaccinated - One dose of Novel OPV2 candidate 1	Group 2: OPV-vaccinated - two doses of novel OPV2 candidate 1	Group 3: OPV-vaccinated - One dose of novel OPV2 candidate 2
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Crohn's Disease			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 4: OPV-vaccinated - Two doses of novel OPV2 candidate 2	Group 5: IPV-vaccinated - Two doses of novel OPV2 candidate 1	Group 6: IPV-vaccinated - Two doses of novel OPV2 candidate 2
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
General disorders and administration site conditions			
Influenza like illness			

subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Crohn's Disease			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 7: IPV-vaccinated - Two doses of placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 17 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			

Crohn's Disease			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Group1: OPV-vaccinated - One dose of Novel OPV2 candidate 1	Group 2: OPV-vaccinated - two doses of novel OPV2 candidate 1	Group 3: OPV-vaccinated - One dose of novel OPV2 candidate 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	44 / 50 (88.00%)	48 / 50 (96.00%)	47 / 50 (94.00%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 50 (0.00%)	2 / 50 (4.00%)	0 / 50 (0.00%)
occurrences (all)	0	3	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Crepitations			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Cyst			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0

Fatigue			
subjects affected / exposed	1 / 50 (2.00%)	3 / 50 (6.00%)	2 / 50 (4.00%)
occurrences (all)	1	3	2
Feeling cold			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Hangover			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	1 / 50 (2.00%)	3 / 50 (6.00%)	4 / 50 (8.00%)
occurrences (all)	1	3	4
Malaise			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
Cystitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Fungal infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			

Dysmenorrhoea			
subjects affected / exposed	3 / 50 (6.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	3	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 50 (2.00%)	2 / 50 (4.00%)	1 / 50 (2.00%)
occurrences (all)	1	3	1
Dyspnoea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
Nasal congestion			
subjects affected / exposed	1 / 50 (2.00%)	3 / 50 (6.00%)	3 / 50 (6.00%)
occurrences (all)	1	3	4
Oropharyngeal pain			
subjects affected / exposed	3 / 50 (6.00%)	8 / 50 (16.00%)	7 / 50 (14.00%)
occurrences (all)	3	12	7
Productive cough			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Burnout syndrome			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	1 / 50 (2.00%)
occurrences (all)	1	1	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
Blood bilirubine			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 50 (6.00%)	5 / 50 (10.00%)	4 / 50 (8.00%)
occurrences (all)	7	6	5
Blood immunoglobulin A decreased			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	1	0	1
Blood potassium increased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	4 / 50 (8.00%)
occurrences (all)	0	1	4
C-reactive protein increased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Eosinophil count increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Lymphocyte percentage decreased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Neutrophil count decreased			

subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
Platelet count increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Wrist fracture			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina Pectoris			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Dizziness			
subjects affected / exposed	0 / 50 (0.00%)	2 / 50 (4.00%)	2 / 50 (4.00%)
occurrences (all)	0	5	3
Dysgeusia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Migraine			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
Paraesthesia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
sleep deficit			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Tension headache			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leucocytosis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	3 / 50 (6.00%)
occurrences (all)	0	1	3
Leucopenia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Middle Ear Disorder			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Eye disorders			

Eye irritation			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 50 (0.00%)	3 / 50 (6.00%)	3 / 50 (6.00%)
occurrences (all)	0	4	3
Abdominal pain lower			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Abnormal faeces			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
Cheilitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Constipation1			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
Dental caries			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	4 / 50 (8.00%)	3 / 50 (6.00%)	3 / 50 (6.00%)
occurrences (all)	4	7	4
Dyspepsia			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
Eructation			

subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Food poisoning			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal sounds abnormal			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease0			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Hyperaesthesia teeth			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	0 / 50 (0.00%)	3 / 50 (6.00%)	5 / 50 (10.00%)
occurrences (all)	0	3	5
Proctalgia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
Rectal Tenesmus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Tongue discomfort			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Toothache			

subjects affected / exposed	0 / 50 (0.00%)	2 / 50 (4.00%)	1 / 50 (2.00%)
occurrences (all)	0	2	1
Vomiting			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
rash generalised			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Swelling face			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 50 (0.00%)	2 / 50 (4.00%)	0 / 50 (0.00%)
occurrences (all)	0	3	0

Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
Arthritis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 50 (2.00%)	3 / 50 (6.00%)	3 / 50 (6.00%)
occurrences (all)	2	4	3
Bursitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
musculoskeletal pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Musculoskeletal stiffness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	2 / 50 (4.00%)	2 / 50 (4.00%)	2 / 50 (4.00%)
occurrences (all)	5	4	4
Neck pain			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			

subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
Bronchitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Ear lobe infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 50 (0.00%)	2 / 50 (4.00%)	0 / 50 (0.00%)
occurrences (all)	0	2	0
Furuncle			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
Gastroenteritis viral			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Herpes simplex			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1

Herpes zoster			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	4 / 50 (8.00%)	4 / 50 (8.00%)	1 / 50 (2.00%)
occurrences (all)	4	4	1
Oral herpes			
subjects affected / exposed	0 / 50 (0.00%)	2 / 50 (4.00%)	0 / 50 (0.00%)
occurrences (all)	0	2	0
Otitis media			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 50 (0.00%)	3 / 50 (6.00%)	0 / 50 (0.00%)
occurrences (all)	0	3	0
Sinusitis			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	1 / 50 (2.00%)
occurrences (all)	2	1	1
Tinea pedis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	9 / 50 (18.00%)	4 / 50 (8.00%)	7 / 50 (14.00%)
occurrences (all)	13	4	8

Urinary tract infection			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Viral rhinitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	1 / 50 (2.00%)
occurrences (all)	1	1	1
Hypophosphataemia			
subjects affected / exposed	2 / 50 (4.00%)	8 / 50 (16.00%)	3 / 50 (6.00%)
occurrences (all)	5	12	5
headache			
subjects affected / exposed	11 / 50 (22.00%)	14 / 50 (28.00%)	16 / 50 (32.00%)
occurrences (all)	12	24	18

Non-serious adverse events	Group 4: OPV-vaccinated - Two doses of novel OPV2 candidate 2	Group 5: IPV-vaccinated - Two doses of novel OPV2 candidate 1	Group 6: IPV-vaccinated - Two doses of novel OPV2 candidate 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	47 / 50 (94.00%)	17 / 17 (100.00%)	15 / 16 (93.75%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 50 (4.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Chest pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	3
Chills			

subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Crepitations			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cyst			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	3 / 16 (18.75%)
occurrences (all)	0	0	7
Feeling cold			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Feeling hot			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hangover			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 50 (2.00%)	1 / 17 (5.88%)	1 / 16 (6.25%)
occurrences (all)	1	1	1
Malaise			
subjects affected / exposed	2 / 50 (4.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Pyrexia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Fungal infection			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			

Seasonal allergy			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	2 / 50 (4.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 50 (4.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	2	1	0
Dyspnoea			
subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	3 / 50 (6.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	4	0	1
Oropharyngeal pain			
subjects affected / exposed	5 / 50 (10.00%)	3 / 17 (17.65%)	1 / 16 (6.25%)
occurrences (all)	5	5	1
Productive cough			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
Rhinorrhoea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Sneezing			

subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	2
Psychiatric disorders			
Burnout syndrome			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 50 (4.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	3	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Blood bilirubine			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	5 / 50 (10.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	7	1	0
Blood immunoglobulin A decreased			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Blood potassium increased			
subjects affected / exposed	4 / 50 (8.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	4	0	1
C-reactive protein increased			
subjects affected / exposed	1 / 50 (2.00%)	1 / 17 (5.88%)	1 / 16 (6.25%)
occurrences (all)	1	1	1
Eosinophil count increased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 50 (2.00%)	1 / 17 (5.88%)	1 / 16 (6.25%)
occurrences (all)	1	1	1
Lymphocyte count decreased			

subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Lymphocyte percentage decreased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Platelet count increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			

Angina Pectoris			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 50 (4.00%)	0 / 17 (0.00%)	4 / 16 (25.00%)
occurrences (all)	2	0	4
Dysgeusia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
sleep deficit			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leucocytosis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Leucopenia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			

Ear pain			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Middle Ear Disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Eye irritation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	4 / 50 (8.00%)	1 / 17 (5.88%)	2 / 16 (12.50%)
occurrences (all)	5	2	2
Abdominal pain lower			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	2 / 50 (4.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	3	0	0
Abnormal faeces			
subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Aphthous ulcer			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Constipation1			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Dental caries			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			

subjects affected / exposed	6 / 50 (12.00%)	6 / 17 (35.29%)	3 / 16 (18.75%)
occurrences (all)	10	6	10
Dyspepsia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	3 / 16 (18.75%)
occurrences (all)	0	0	3
Eructation			
subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Flatulence			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	2 / 16 (12.50%)
occurrences (all)	1	0	4
Food poisoning			
subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorder			
subjects affected / exposed	3 / 50 (6.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	3	0	0
Gastrointestinal sounds abnormal			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease0			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Hyperaesthesia teeth			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 50 (2.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Proctalgia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rectal Tenesmus			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Swollen tongue			

subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tongue discomfort			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	3 / 50 (6.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	3	0	0
Vomiting			
subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Dermatitis allergic			
subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
rash generalised			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Swelling face			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
subjects affected / exposed	3 / 50 (6.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	3	0	1
Arthritis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	2
Bursitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
musculoskeletal pain			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	4
Myalgia			

subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	2 / 16 (12.50%)
occurrences (all)	0	1	2
Neck pain			
subjects affected / exposed	3 / 50 (6.00%)	1 / 17 (5.88%)	1 / 16 (6.25%)
occurrences (all)	3	1	1
Pain in extremity			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Rotator cuff syndrome			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	1 / 50 (2.00%)	2 / 17 (11.76%)	0 / 16 (0.00%)
occurrences (all)	1	2	0
Bronchitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Ear lobe infection			
subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Enterobiasis			
subjects affected / exposed	1 / 50 (2.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Furuncle			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	2	0	1

Gastroenteritis viral			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 50 (4.00%)	5 / 17 (29.41%)	1 / 16 (6.25%)
occurrences (all)	2	5	1
Oral herpes			
subjects affected / exposed	1 / 50 (2.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Otitis media			
subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Rash pustular			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 17 (5.88%)	2 / 16 (12.50%)
occurrences (all)	0	1	2
Sinusitis			
subjects affected / exposed	2 / 50 (4.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0

Tinea pedis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	13 / 50 (26.00%)	0 / 17 (0.00%)	5 / 16 (31.25%)
occurrences (all)	13	0	6
Urinary tract infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Viral rhinitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 17 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	5 / 50 (10.00%)	0 / 17 (0.00%)	2 / 16 (12.50%)
occurrences (all)	6	0	3
headache			
subjects affected / exposed	14 / 50 (28.00%)	6 / 17 (35.29%)	5 / 16 (31.25%)
occurrences (all)	18	9	10

Non-serious adverse events	Group 7: IPV-vaccinated - Two doses of placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 17 (100.00%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			

subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Chest pain				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences (all)	1			
Chills				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences (all)	1			
Crepitations				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Cyst				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Fatigue				
subjects affected / exposed	3 / 17 (17.65%)			
occurrences (all)	6			
Feeling cold				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Feeling hot				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Hangover				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences (all)	2			
Influenza like illness				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences (all)	1			
Malaise				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences (all)	1			
Pyrexia				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Cystitis				

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Fungal infection			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Oral candidiasis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	3		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 17 (17.65%)		
occurrences (all)	3		
Dyspnoea			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Dyspnoea exertional			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Epistaxis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Oropharyngeal pain			
subjects affected / exposed	3 / 17 (17.65%)		
occurrences (all)	6		
Productive cough			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Sneezing			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Burnout syndrome			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Blood bilirubine			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	4		
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	2		
Blood immunoglobulin A decreased			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Blood potassium increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
C-reactive protein increased			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Eosinophil count increased			

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Lymphocyte count decreased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Lymphocyte percentage decreased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Neutrophil count decreased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Neutrophil count increased			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Platelet count increased			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Head injury			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Procedural nausea			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Procedural pain			

subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Wrist fracture			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Angina Pectoris			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Palpitations			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	2		
Dysgeusia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
sleep deficit			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Tension headache			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Blood and lymphatic system disorders			

Leucocytosis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Leucopenia			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Middle Ear Disorder			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Eye disorders			
Eye irritation			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	4 / 17 (23.53%)		
occurrences (all)	8		
Abdominal pain lower			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Abdominal pain upper			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Abnormal faeces			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Aphthous ulcer			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Cheilitis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Constipation1			

subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Dental caries				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences (all)	1			
Diarrhoea				
subjects affected / exposed	3 / 17 (17.65%)			
occurrences (all)	4			
Dyspepsia				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Eructation				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Flatulence				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Food poisoning				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Gastrointestinal disorder				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Gastrointestinal sounds abnormal				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Gastrooesophageal reflux disease0				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Hyperaesthesia teeth				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Nausea				
subjects affected / exposed	2 / 17 (11.76%)			
occurrences (all)	4			
Proctalgia				

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Rectal Tenesmus			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Swollen tongue			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Tongue discomfort			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	2 / 17 (11.76%)		
occurrences (all)	2		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Dermatitis allergic			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Eczema			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Night sweats			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		

Rash subjects affected / exposed occurrences (all) rash generalised subjects affected / exposed occurrences (all) Swelling face subjects affected / exposed occurrences (all) Urticaria subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0 0 / 17 (0.00%) 0 1 / 17 (5.88%) 1 0 / 17 (0.00%) 0		
Renal and urinary disorders Dysuria subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Musculoskeletal and connective tissue disorders arthralgia subjects affected / exposed occurrences (all) Arthritis subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Bursitis subjects affected / exposed occurrences (all) Muscle spasms subjects affected / exposed occurrences (all) Musculoskeletal chest pain subjects affected / exposed occurrences (all) musculoskeletal pain	0 / 17 (0.00%) 0 0 / 17 (0.00%) 0 2 / 17 (11.76%) 4 0 / 17 (0.00%) 0 1 / 17 (5.88%) 1 0 / 17 (0.00%) 0		

subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Musculoskeletal stiffness			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	3 / 17 (17.65%)		
occurrences (all)	8		
Neck pain			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Rotator cuff syndrome			
subjects affected / exposed	1 / 17 (5.88%)		
occurrences (all)	1		
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Ear infection			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Ear lobe infection			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		
Enterobiasis			
subjects affected / exposed	0 / 17 (0.00%)		
occurrences (all)	0		

Furuncle				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Gastroenteritis viral				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Herpes simplex				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Herpes zoster				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Infection				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences (all)	1			
Oral herpes				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences (all)	1			
Otitis media				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	0 / 17 (0.00%)			
occurrences (all)	0			
Rash pustular				
subjects affected / exposed	1 / 17 (5.88%)			
occurrences (all)	1			

Rhinitis subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Sinusitis subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Tinea pedis subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	9 / 17 (52.94%) 10		
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Viral rhinitis subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0		
Hypoglycaemia subjects affected / exposed occurrences (all)	1 / 17 (5.88%) 1		
Hypophosphataemia subjects affected / exposed occurrences (all)	2 / 17 (11.76%) 3		
headache subjects affected / exposed occurrences (all)	7 / 17 (41.18%) 16		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 December 2018	In case of extended shedding of the subjects sampling of household contacts will be offered to the subjects' households: this is explained in appendix 4 and also added at section 1.3.1 'Potential Risks'. Frequency of follow-up samples to be taken in case of extended shedding has been adapted: 'every 3 weeks' has been deleted and subjects will be asked to collect further 3 consecutive stool samples (with a maximum of one sample per day) after the last per-protocol sample as soon as these PCR-positive results are known (anticipated approximately 3 weeks after the last such sample provided for evaluation) and to repeat this until shedding is PCR-negative for type 2 poliovirus on 3 consecutive stool samples, which then determines study end for this person. This is adapted accordingly in the following sections: synopsis 'Study/treatment duration', section 9.1 'Study Completion' and in Appendix 4. The DSMB will also monitor study enrollment, particularly for IPV-vaccinated subjects, and recommend truncation and/or closure of study groups if enrollment stagnates and when current enrollment is considered sufficient to meet study objectives and no safety signals occurred. The minimum number of IPV-vaccinated subjects agreed on by DSMB per candidate vaccine is 24. With a randomization of 2:1 for placebo the minimum study cohort size for Groups 5, 6 and 7 will be 16. In case of safety signals the DSMB reserves the right to reverse the truncated enrollment. This explanation is added in sections: Synopsis 'Overview of Study Design', section 4.1 'Overview of Study Design' and section 6.6 'Randomization and Blinding'. Safety endpoint evaluation by age group for IPV- vaccinated subjects has been deleted in synopsis and section 3.1 'Primary endpoints' and section 3.2 'Secondary endpoints' Affiliation of statistician has been changed on signature page and section of Study Administrative Structure.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported