Clinical trial results:
A Phase III, observer-blind, randomized, multicenter study to evaluate immunogenicity, reactogenicity and safety of GlaxoSmithKline (GSK) Biologicals' Rotarix Porcine circovirus (PCV)-free liquid as compared to GSK's Rotarix liquid, given in 2doses in healthy Chinese infants starting at age 6-16 weeks

Summary

EudraCT number	2020-000972-38
Trial protocol	Outside EU/EEA
Global end of trial date	23 October 2024

Results information

Result version number	v1 (current)
This version publication date	09 May 2025
First version publication date	09 May 2025

Trial information

Trial identification

Sponsor protocol code	212692

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT06025695
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue del'Institut, 89, Rixensart, Belgium, 1330
Public contact	GSK Response Center, GlaxoSmithKline, 044 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 044 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	19 December 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 October 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this study is to evaluate the immunogenicity, reactogenicity and safety of GSK's HRV PCV-free vaccine compared to HRV vaccine in healthy Chinese infants 6-16 weeks of age.

Protection of trial subjects:

The participants were observed closely for at least 30 minutes after the administration of the study interventions. Appropriate medical treatment was readily available during the observation period in case of anaphylaxis and/or syncope.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2023
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	China: 2000
Worldwide total number of subjects	2000
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	2000
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted in China.

Pre-assignment

Screening details:

One participant was randomized to the HRV group but was vaccinated in the HRV PCV-free group. Data for this participant was analyzed in the HRV PCV-free group for all analyses.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Human Rotavirus (HRV) Group

Arm description:

Participants received 2 doses of GSK's liquid oral live attenuated HRV study intervention at Day 1 and Month 1.

Arm type	Active comparator
Investigational medicinal product name	GSK's liquid oral live attenuated human rotavirus (HRV) vaccine
Investigational medicinal product code	
Other name	Rotarix
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

2 doses per participant

Arm title	HRV Porcine Circovirus (PCV)-free Group

Arm description:

Participants received 2 doses of the PCV-free liquid formulation of GSK's oral live attenuated HRV study intervention at Day 1 and Month 1.

Arm type	Experimental
Investigational medicinal product name	Porcine circovirus (PCV)-free liquid formulation of GlaxoSmithKline Biologicals SA (GSK) oral live attenuated human rotavirus (HRV) vaccine
Investigational medicinal product code	
Other name	Rotarix PCV-free
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

2 doses per participant

Number of subjects in period 1	Human Rotavirus (HRV) Group	HRV Porcine Circovirus (PCV)-free Group
Started	998	1002
Completed	956	967
Not completed	42	35
Migrated / Moved from the Study Area	13	10
Adverse event, non-fatal	5	6
Not Specified	23	19
Adverse Event Requiring Expedited Report	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Human Rotavirus (HRV) Group
Reporting group description:	
Participants received 2 doses of GSK's liquid oral live attenuated HRV study intervention at Day 1 and Month 1.	
Reporting group title	HRV Porcine Circovirus (PCV)-free Group
Reporting group description:	
Participants received 2 doses of the PCV-free liquid formulation of GSK's oral live attenuated HRV study intervention at Day 1 and Month 1.	

Reporting group values	Human Rotavirus (HRV) Group	HRV Porcine Circovirus (PCV)-free Group	Total
Number of subjects	998	1002	2000
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	998	1002	2000
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Sex: Female, Male Units: Participants			
MALE	543	490	1033
FEMALE	455	512	967
Race/Ethnicity, Customized Units: Subjects			
ASIAN - EAST ASIAN HERITAGE	998	1002	2000

End points

End points reporting groups

Reporting group title	Human Rotavirus (HRV) Group
Reporting group description:	
Participants received 2 doses of GSK's liquid oral live attenuated HRV study intervention at Day 1 and Month 1.	
Reporting group title	HRV Porcine Circovirus (PCV)-free Group
Reporting group description:	
Participants received 2 doses of the PCV-free liquid formulation of GSK's oral live attenuated HRV study intervention at Day 1 and Month 1.	

Primary: Percentage of participants with anti-rotavirus (RV) immunoglobulin A (IgA) antibody (Ab) seroconversion rate

End point title	Percentage of participants with anti-rotavirus (RV) immunoglobulin A (IgA) antibody (Ab) seroconversion rate
End point description:	
Seroconversion rate is defined as the percentage of participants who were initially seronegative (i.e., with anti-RV IgA Ab concentration below [<] 20 unit per milliliter [U/mL] prior the first dose of study intervention) and developed anti-RV IgA Ab concentration greater than or equal to (>=) 20 U/mL at Month 2 (1-month post-Dose 2). Analysis was performed on Per Protocol Set (PPS), which includes all participants who adhered to the study protocol, ensuring they received no unapproved treatments, remained blinded, had anti-RV concentration <20 U/mL before intervention, had available anti-RV results at Month 2, complied with blood sampling schedules, and had no concurrent infections. Only participants with data available at specified timepoints were included in the analysis.	
End point type	Primary
End point timeframe:	
At Month 2 (1-month post-dose 2)	

End point values	Human Rotavirus (HRV) Group	HRV Porcine Circovirus (PCV)-free Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	865	870		
Units: Percentage of participants				
number (confidence interval 95%)	88.7 (86.4 to 90.7)	84.9 (82.4 to 87.3)		

Statistical analyses

Statistical analysis title	Between-group analysis
Statistical analysis description:	
To demonstrate the immunological non-inferiority of HRV PCV-free Group as compared to HRV Group in terms of seroconversion rates 1 month post Dose 2	
Comparison groups	Human Rotavirus (HRV) Group v HRV Porcine Circovirus (PCV)-free Group

Number of subjects included in analysis	1735
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in seroconversion rate
Point estimate	-3.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.93
upper limit	-0.55

Primary: Serum anti-RV IgA Ab concentrations expressed as Geometric Mean Concentrations (GMCs)

End point title	Serum anti-RV IgA Ab concentrations expressed as Geometric Mean Concentrations (GMCs)

End point description:

Analysis was performed on PPS. Only participants with data available at the specified timepoints were included in this analysis.

End point type	Primary

End point timeframe:

At Month 2 (1-month post-Dose 2)

End point values	Human Rotavirus (HRV) Group	HRV Porcine Circovirus (PCV)-free Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	865	870		
Units: U/mL				
geometric mean (confidence interval 95%)	222.82 (198.03 to 250.71)	157.31 (139.31 to 177.64)		

Statistical analyses

Statistical analysis title	Between-group analysis

Statistical analysis description:

To demonstrate the non-inferiority of the HRV PCV-free Group as compared to HRV Group in terms of serum anti-RV IgA Ab concentrations 1 month post Dose 2.

Comparison groups	Human Rotavirus (HRV) Group v HRV Porcine Circovirus (PCV)-free Group

Number of subjects included in analysis	1735
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	GMC Ratio
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	0.84

Secondary: Percentage of participants with serum anti-RV IgA Ab concentrations >= 90 U/mL

End point title	Percentage of participants with serum anti-RV IgA Ab concentrations >= 90 U/mL

End point description:

Analysis was performed on PPS. Only participants with data available at the specified timepoints were included in this analysis.

End point type	Secondary

End point timeframe:

At Month 2 (1-month post-Dose 2)

End point values	Human Rotavirus (HRV) Group	HRV Porcine Circovirus (PCV)-free Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	865	870		
Units: Percentage of participants				
number (confidence interval 95%)	69.2 (66.1 to 72.3)	62.9 (59.6 to 66.1)		

Statistical analyses

Statistical analysis title	Between-group analysis

Statistical analysis description:

To demonstrate the immunological non-inferiority of HRV PCV-free Group as compared to HRV Group in terms of percentage of participants with anti-RV IgA antibody concentrations >=90 U/mL 1 month post Dose 2.

Comparison groups	Human Rotavirus (HRV) Group v HRV Porcine Circovirus (PCV)-free Group

Number of subjects included in analysis	1735
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	-6.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.81
upper limit	-1.92

Secondary: Number of participants reporting solicited systemic events

End point title	Number of participants reporting solicited systemic events

End point description:

Solicited systemic events include fever/pyrexia, diarrhoea, vomiting, irritability/fussiness, loss of appetite, cough/runny nose. Fever is defined as body temperature >= 37.5 degrees Celsius (°C) and the preferred location for measuring temperature is the axilla. Any = occurrence of the event regardless of intensity grade or relation to the study vaccination. Analysis was performed on the Exposed Set which includes all participants with at least 1 dose of the study intervention administered and with the solicited systemic events diary card data available after the corresponding vaccination for the specified timepoint.

End point type	Secondary

End point timeframe:

Within 14 days (the day of vaccination and 13 subsequent days) after each vaccination (occurring at Day 1 and Month 1)

End point values	Human Rotavirus (HRV) Group	HRV Porcine Circovirus (PCV)-free Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	973	986		
Units: Participants				
Cough/Runny Nose, post vaccination at Day 1	158	200		
Cough/Runny Nose, post vaccination at Month 1	131	157		
Diarrhoea, post vaccination at Day 1	66	66		
Diarrhoea, post vaccination at Month 1	38	40		
Fever/Pyrexia, post vaccination at Day 1	122	100		
Fever/Pyrexia, post vaccination at Month 1	104	91		
Irritability, post vaccination at Day 1	126	150		
Irritability, post vaccination at Month 1	61	59		
Loss of appetite, post vaccination at Day 1	73	92		
Loss of appetite, post vaccination at Month 1	32	34		
Vomiting, post vaccination at Day 1	71	69		
Vomiting, post vaccination at Month 1	30	36		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants reporting unsolicited adverse events (AEs)

End point title	Number of participants reporting unsolicited adverse events (AEs)

End point description:

Unsolicited AEs include any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as an unsolicited adverse event. Any = occurrence the event regardless of intensity grade or relation to the study vaccination. Analysis was performed on the Exposed Set which includes all participants with at least 1 dose of the study intervention administered and for whom unsolicited AEs data were available after the corresponding vaccination for the specified timepoint.

End point type	Secondary

End point timeframe:

Within 31 days (the day of vaccination and 30 subsequent days) after each vaccination (occurring at Day 1 and Month 1)

End point values	Human Rotavirus (HRV) Group	HRV Porcine Circovirus (PCV)-free Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	998	1002		
Units: Participants				
Post-vaccination at Day 1	236	234		
Post-vaccination at Month 1	223	229		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants reporting serious adverse events (SAEs)

End point title	Number of participants reporting serious adverse events (SAEs)

End point description:

An SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization or results in disability/incapacity or in other situations that are considered serious as per medical or scientific judgment. Any = occurrence of the SAE regardless of intensity grade or relation to the study vaccination. Analysis was performed on the Exposed Set which includes all participants with at least 1 dose of the study intervention administered and for whom SAE data were available after the corresponding vaccination for the specified timepoint.

End point type	Secondary

End point timeframe:
From Day 1 to Month 7

End point values	Human Rotavirus (HRV) Group	HRV Porcine Circovirus (PCV)-free Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	998	1002		
Units: Participants	251	262		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs: during the 14-day follow-up period (from Day 1 to Day 14) after any vaccination and unsolicited AEs: during the 31-day follow-up period after any vaccination (from Day 1 to Day 31). All cause mortality and SAEs: From Day 1 to Month 7.

Adverse event reporting additional description:

SAEs, solicited AEs and unsolicited AEs were reported for the Exposed set.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	HRV Porcine Circovirus (PCV)-free Group

Reporting group description:

Participants received 2 doses of the PCV-free liquid formulation of GSK's oral live attenuated HRV study intervention at Day 1 and Month 1.

Reporting group title	Human Rotavirus (HRV) Group

Reporting group description:

Participants received 2 doses of GSK's liquid oral live attenuated HRV study intervention at Day 1 and Month 1.

Serious adverse events	HRV Porcine Circovirus (PCV)-free Group	Human Rotavirus (HRV) Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	262 / 1002 (26.15%)	251 / 998 (25.15%)	
number of deaths (all causes)	0	1	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lymphangioma			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Shock			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Food allergy			

subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	6 / 1002 (0.60%)	3 / 998 (0.30%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Craniocerebral injury			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Skull fracture			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Congenital megacolon			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniosynostosis			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular malformation			

subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	4 / 1002 (0.40%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure acute			
subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	2 / 1002 (0.20%)	2 / 998 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coordination abnormal			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Immune thrombocytopenia			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Gastrointestinal disorders			
Enteritis			
subjects affected / exposed	5 / 1002 (0.50%)	6 / 998 (0.60%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infantile diarrhoea			
subjects affected / exposed	4 / 1002 (0.40%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	2 / 1002 (0.20%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Functional gastrointestinal disorder			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorder			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated inguinal hernia			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intussusception			

subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mouth ulceration			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Liver injury			
subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	1 / 1002 (0.10%)	2 / 998 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	2 / 1002 (0.20%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	2 / 1002 (0.20%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis atopic			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	11 / 1002 (1.10%)	11 / 998 (1.10%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	

Febrile infection			
subjects affected / exposed	20 / 1002 (2.00%)	21 / 998 (2.10%)	
occurrences causally related to treatment / all	0 / 22	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	36 / 1002 (3.59%)	39 / 998 (3.91%)	
occurrences causally related to treatment / all	0 / 37	0 / 41	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	138 / 1002 (13.77%)	140 / 998 (14.03%)	
occurrences causally related to treatment / all	0 / 160	0 / 163	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal infection			
subjects affected / exposed	8 / 1002 (0.80%)	3 / 998 (0.30%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	6 / 1002 (0.60%)	6 / 998 (0.60%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	6 / 1002 (0.60%)	6 / 998 (0.60%)	
occurrences causally related to treatment / all	0 / 6	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	13 / 1002 (1.30%)	5 / 998 (0.50%)	
occurrences causally related to treatment / all	0 / 14	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	3 / 1002 (0.30%)	3 / 998 (0.30%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterobacter pneumonia			

subjects affected / exposed	3 / 1002 (0.30%)	2 / 998 (0.20%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia escherichia			
subjects affected / exposed	0 / 1002 (0.00%)	4 / 998 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia staphylococcal			
subjects affected / exposed	1 / 1002 (0.10%)	3 / 998 (0.30%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	6 / 1002 (0.60%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	5 / 1002 (0.50%)	2 / 998 (0.20%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia haemophilus			
subjects affected / exposed	4 / 1002 (0.40%)	3 / 998 (0.30%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
subjects affected / exposed	4 / 1002 (0.40%)	3 / 998 (0.30%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	2 / 1002 (0.20%)	5 / 998 (0.50%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngopharyngitis			

subjects affected / exposed	1 / 1002 (0.10%)	6 / 998 (0.60%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpangina			
subjects affected / exposed	5 / 1002 (0.50%)	3 / 998 (0.30%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngitis			
subjects affected / exposed	3 / 1002 (0.30%)	7 / 998 (0.70%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia klebsiella			
subjects affected / exposed	2 / 1002 (0.20%)	2 / 998 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	2 / 1002 (0.20%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			
subjects affected / exposed	2 / 1002 (0.20%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia mycoplasmal			
subjects affected / exposed	1 / 1002 (0.10%)	2 / 998 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis mycoplasmal			
subjects affected / exposed	3 / 1002 (0.30%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			

subjects affected / exposed	3 / 1002 (0.30%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis mycoplasmal			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheitis			
subjects affected / exposed	0 / 1002 (0.00%)	2 / 998 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exanthema subitum			
subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis adenovirus			
subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia parainfluenzae viral			
subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchiolitis			

subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis bacterial			
subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pertussis			
subjects affected / exposed	2 / 1002 (0.20%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycoplasma infection			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis bacterial			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coxsackie viral infection			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis bacterial			
subjects affected / exposed	2 / 1002 (0.20%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia respiratory syncytial viral			

subjects affected / exposed	0 / 1002 (0.00%)	2 / 998 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pneumococcal			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pseudomonal			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial diarrhoea			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis mycoplasmal			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronavirus pneumonia			

subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal bacterial infection			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemophilus infection			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand-foot-and-mouth disease			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impetigo			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media acute			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia moraxella			

subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia streptococcal			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicella			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	HRV Porcine Circovirus (PCV)-free Group	Human Rotavirus (HRV) Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	617 / 1002 (61.58%)	596 / 998 (59.72%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Haemangioma of skin			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	178 / 1002 (17.76%)	178 / 998 (17.84%)	
occurrences (all)	195	201	
Peripheral swelling			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Transient hypogammaglobulinaemia of infancy			
subjects affected / exposed	2 / 1002 (0.20%)	2 / 998 (0.20%)	
occurrences (all)	2	2	
Respiratory, thoracic and mediastinal disorders			
Nasal obstruction			
subjects affected / exposed	25 / 1002 (2.50%)	35 / 998 (3.51%)	
occurrences (all)	26	39	
Rhinorrhoea			
subjects affected / exposed	81 / 1002 (8.08%)	61 / 998 (6.11%)	
occurrences (all)	86	62	
Cough			
subjects affected / exposed	87 / 1002 (8.68%)	91 / 998 (9.12%)	
occurrences (all)	94	96	
Nasal congestion			
subjects affected / exposed	13 / 1002 (1.30%)	9 / 998 (0.90%)	
occurrences (all)	14	9	
Sneezing			
subjects affected / exposed	6 / 1002 (0.60%)	9 / 998 (0.90%)	
occurrences (all)	8	9	
Productive cough			

subjects affected / exposed	1 / 1002 (0.10%)	3 / 998 (0.30%)	
occurrences (all)	1	3	
Pharyngeal erythema			
subjects affected / exposed	2 / 1002 (0.20%)	2 / 998 (0.20%)	
occurrences (all)	2	2	
Sputum retention			
subjects affected / exposed	2 / 1002 (0.20%)	1 / 998 (0.10%)	
occurrences (all)	2	1	
Pharyngeal swelling			
subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences (all)	1	1	
Dysphonia			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Increased upper airway secretion			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Laryngeal obstruction			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Rhinitis allergic			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Hypoventilation neonatal			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Oropharyngeal pain			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Wheezing			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Irritability			
subjects affected / exposed	155 / 1002 (15.47%)	149 / 998 (14.93%)	
occurrences (all)	191	179	

Sleep terror			
subjects affected / exposed	2 / 1002 (0.20%)	0 / 998 (0.00%)	
occurrences (all)	3	0	
Investigations			
Myocardial necrosis marker increased			
subjects affected / exposed	9 / 1002 (0.90%)	10 / 998 (1.00%)	
occurrences (all)	9	11	
Immunoglobulins decreased			
subjects affected / exposed	2 / 1002 (0.20%)	2 / 998 (0.20%)	
occurrences (all)	2	2	
Liver function test abnormal			
subjects affected / exposed	3 / 1002 (0.30%)	1 / 998 (0.10%)	
occurrences (all)	3	1	
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 1002 (0.10%)	2 / 998 (0.20%)	
occurrences (all)	1	2	
Bile acids increased			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Occult blood positive			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Transaminases increased			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences (all)	1	1	
Congenital laryngeal stridor			
subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences (all)	1	1	
Ventricular septal defect			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	

Congenital laryngeal malformation subjects affected / exposed occurrences (all)	1 / 1002 (0.10%) 2	0 / 998 (0.00%) 0	
Cardiac disorders Myocardial injury subjects affected / exposed occurrences (all)	7 / 1002 (0.70%) 7	3 / 998 (0.30%) 3	
Sinus arrhythmia subjects affected / exposed occurrences (all)	0 / 1002 (0.00%) 0	1 / 998 (0.10%) 1	
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 1002 (0.00%) 0	1 / 998 (0.10%) 1	
Myocarditis subjects affected / exposed occurrences (all)	1 / 1002 (0.10%) 1	0 / 998 (0.00%) 0	
Nervous system disorders Drooling subjects affected / exposed occurrences (all)	1 / 1002 (0.10%) 1	0 / 998 (0.00%) 0	
Somnolence subjects affected / exposed occurrences (all)	1 / 1002 (0.10%) 1	0 / 998 (0.00%) 0	
Blood and lymphatic system disorders Coagulopathy subjects affected / exposed occurrences (all)	1 / 1002 (0.10%) 1	2 / 998 (0.20%) 2	
Anaemia subjects affected / exposed occurrences (all)	1 / 1002 (0.10%) 1	5 / 998 (0.50%) 5	
Neutropenia subjects affected / exposed occurrences (all)	0 / 1002 (0.00%) 0	2 / 998 (0.20%) 2	
Granulocytopenia subjects affected / exposed occurrences (all)	0 / 1002 (0.00%) 0	1 / 998 (0.10%) 1	
Hypofibrinogenaemia			

subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Leukopenia			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Secondary thrombocytosis			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Agranulocytosis			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Thrombocytopenia			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
Eye discharge			
subjects affected / exposed	0 / 1002 (0.00%)	3 / 998 (0.30%)	
occurrences (all)	0	3	
Dacryostenosis acquired			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Blepharitis			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Keratitis			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	95 / 1002 (9.48%)	85 / 998 (8.52%)	
occurrences (all)	106	98	
Diarrhoea			
subjects affected / exposed	118 / 1002 (11.78%)	123 / 998 (12.32%)	
occurrences (all)	131	133	
Constipation			

subjects affected / exposed	18 / 1002 (1.80%)	13 / 998 (1.30%)	
occurrences (all)	18	13	
Abdominal distension			
subjects affected / exposed	3 / 1002 (0.30%)	2 / 998 (0.20%)	
occurrences (all)	3	2	
Infantile diarrhoea			
subjects affected / exposed	3 / 1002 (0.30%)	2 / 998 (0.20%)	
occurrences (all)	3	2	
Functional gastrointestinal disorder			
subjects affected / exposed	4 / 1002 (0.40%)	1 / 998 (0.10%)	
occurrences (all)	4	1	
Haematochezia			
subjects affected / exposed	1 / 1002 (0.10%)	3 / 998 (0.30%)	
occurrences (all)	1	4	
Gastrointestinal disorder			
subjects affected / exposed	3 / 1002 (0.30%)	1 / 998 (0.10%)	
occurrences (all)	4	1	
Enteritis			
subjects affected / exposed	1 / 1002 (0.10%)	2 / 998 (0.20%)	
occurrences (all)	1	2	
Flatulence			
subjects affected / exposed	3 / 1002 (0.30%)	0 / 998 (0.00%)	
occurrences (all)	4	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 1002 (0.20%)	0 / 998 (0.00%)	
occurrences (all)	2	0	
Abdominal pain			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Abdominal tenderness			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Dry mouth			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Gingival cyst			

subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Infantile colic			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Inguinal hernia			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Mucous stools			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Dyschezia			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Regurgitation			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Mouth ulceration			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Dyspepsia			
subjects affected / exposed	7 / 1002 (0.70%)	9 / 998 (0.90%)	
occurrences (all)	7	9	
Hepatobiliary disorders			
Liver injury			
subjects affected / exposed	3 / 1002 (0.30%)	4 / 998 (0.40%)	
occurrences (all)	3	4	
Hepatic function abnormal			
subjects affected / exposed	2 / 1002 (0.20%)	1 / 998 (0.10%)	
occurrences (all)	2	1	
Hypercholia			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Cholestasis			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	

Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	18 / 1002 (1.80%)	17 / 998 (1.70%)	
occurrences (all)	18	19	
Rash			
subjects affected / exposed	4 / 1002 (0.40%)	6 / 998 (0.60%)	
occurrences (all)	4	6	
Dermatitis allergic			
subjects affected / exposed	1 / 1002 (0.10%)	2 / 998 (0.20%)	
occurrences (all)	1	2	
Eczema asteatotic			
subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences (all)	1	1	
Dermatitis atopic			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Eczema infantile			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Pityriasis			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Rash erythematous			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Dermatitis diaper			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Purpura			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Rash papular			

subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Endocrine disorders			
Transient neonatal hyperthyrotropinaemia			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Infections and infestations			
Pneumonia			
subjects affected / exposed	6 / 1002 (0.60%)	2 / 998 (0.20%)	
occurrences (all)	6	2	
Upper respiratory tract infection			
subjects affected / exposed	45 / 1002 (4.49%)	46 / 998 (4.61%)	
occurrences (all)	55	48	
Bronchitis			
subjects affected / exposed	14 / 1002 (1.40%)	13 / 998 (1.30%)	
occurrences (all)	14	13	
Pharyngitis			
subjects affected / exposed	9 / 1002 (0.90%)	14 / 998 (1.40%)	
occurrences (all)	9	15	
Nasopharyngitis			
subjects affected / exposed	9 / 1002 (0.90%)	8 / 998 (0.80%)	
occurrences (all)	9	8	
Gastroenteritis			
subjects affected / exposed	7 / 1002 (0.70%)	8 / 998 (0.80%)	
occurrences (all)	7	8	
Respiratory tract infection			
subjects affected / exposed	219 / 1002 (21.86%)	181 / 998 (18.14%)	
occurrences (all)	255	203	
Laryngitis			
subjects affected / exposed	4 / 1002 (0.40%)	4 / 998 (0.40%)	
occurrences (all)	4	4	
Candida infection			
subjects affected / exposed	1 / 1002 (0.10%)	2 / 998 (0.20%)	
occurrences (all)	1	2	
Influenza			

subjects affected / exposed	2 / 1002 (0.20%)	1 / 998 (0.10%)	
occurrences (all)	2	1	
Rhinitis			
subjects affected / exposed	2 / 1002 (0.20%)	1 / 998 (0.10%)	
occurrences (all)	2	1	
Conjunctivitis			
subjects affected / exposed	0 / 1002 (0.00%)	2 / 998 (0.20%)	
occurrences (all)	0	2	
Cytomegalovirus infection			
subjects affected / exposed	0 / 1002 (0.00%)	2 / 998 (0.20%)	
occurrences (all)	0	2	
Oral candidiasis			
subjects affected / exposed	0 / 1002 (0.00%)	2 / 998 (0.20%)	
occurrences (all)	0	2	
Adenovirus infection			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Acute sinusitis			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Sinusitis			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Mycoplasma infection			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Herpangina			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Gastrointestinal infection			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Exanthema subitum			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Eczema infected			

subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Diarrhoea infectious			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Dermatitis infected			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Dacryocystitis			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Bronchiolitis			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Gastroenteritis rotavirus			
subjects affected / exposed	2 / 1002 (0.20%)	0 / 998 (0.00%)	
occurrences (all)	2	0	
Rhinovirus infection			
subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences (all)	1	1	
Chlamydial infection			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Otitis media			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Hand-foot-and-mouth disease			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Enterobacter infection			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Conjunctivitis bacterial			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			

Decreased appetite			
subjects affected / exposed	102 / 1002 (10.18%)	91 / 998 (9.12%)	
occurrences (all)	114	104	
Electrolyte imbalance			
subjects affected / exposed	8 / 1002 (0.80%)	4 / 998 (0.40%)	
occurrences (all)	8	5	
Hyperlactacidaemia			
subjects affected / exposed	3 / 1002 (0.30%)	1 / 998 (0.10%)	
occurrences (all)	3	1	
Hyperkalaemia			
subjects affected / exposed	0 / 1002 (0.00%)	3 / 998 (0.30%)	
occurrences (all)	0	3	
Hypercalcaemia			
subjects affected / exposed	1 / 1002 (0.10%)	2 / 998 (0.20%)	
occurrences (all)	1	2	
Lactic acidosis			
subjects affected / exposed	0 / 1002 (0.00%)	1 / 998 (0.10%)	
occurrences (all)	0	1	
Dehydration			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Vitamin K deficiency			
subjects affected / exposed	1 / 1002 (0.10%)	0 / 998 (0.00%)	
occurrences (all)	1	0	
Acid-base balance disorder mixed			
subjects affected / exposed	1 / 1002 (0.10%)	1 / 998 (0.10%)	
occurrences (all)	1	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported