



Clinical trial results:

A Phase III, Single-Arm, Open-Label Study to Evaluate the Safety, Pharmacokinetics, Anti-Drug Antibody, and Anti-RSV Neutralizing Antibody Following Administration of 2 Doses of Nirsevimab Given 5 to 6 Months Apart in Infants with Congenital Heart Disease, Chronic Lung Disease, Immunocompromise, Down Syndrome, or Born Pre-Term in Japan (JUBILUS)

Summary

EudraCT number	2025-000021-13
Trial protocol	Outside EU/EEA
Global end of trial date	24 July 2025

Results information

Result version number	v1 (current)
This version publication date	04 February 2026
First version publication date	04 February 2026

Trial information

Trial identification

Sponsor protocol code	D5290C00009
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT06042049
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AstraZeneca
Sponsor organisation address	1800 Concorde Pike, Wilmington, United States, DE 19803
Public contact	Global Clinical Lead, AstraZeneca, +1 8772409479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca, +1 8772409479, information.center@astrazeneca.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	24 July 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 July 2025
Global end of trial reached?	Yes
Global end of trial date	24 July 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability of 2 doses of nirsevimab administered 5 to 6 months apart in Infants with Congenital Heart Disease, Chronic Lung Disease, Immunocompromise, Down Syndrome, or Born Pre-Term in Japan

Protection of trial subjects:

This study was performed in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with International Council for Harmonisation/Good Clinical Practice, applicable regulatory requirements, and the AstraZeneca policy on Bioethics.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 July 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	Japan: 33
Worldwide total number of subjects	33
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)	8
Infants and toddlers (28 days-23 months)	25
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 Phase III, single-arm, open-label study was conducted at 9 investigational sites in Japan in infants (< or equal to 12 months of age at enrolment) with congenital heart disease, chronic lung disease, immunocompromise, down syndrome, or born pre-term.

Pre-assignment

Screening details:

The study had a screening visit (Day -30 to Day 1), study drug given in 2 doses (Day 1 and Day 150-180), and an end-of-study follow-up (360 days after the second or last dose). A total of 33 infants were enrolled. Final results are presented up to the last subject, last visit (LSLV) date of 24-Jul-2025.

Period 1

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

Arms

Arm title	Nirsevimab 50 mg/100 mg
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Arm description:

Participants in the first year of life received the first dose of nirsevimab on Day 1 as a single, fixed IM dose of 50 mg if body weight was <5 kg or 100 mg if body weight was ≥5 kg. A second fixed IM dose of 50 mg was administered if body weight was <5 kg or 100 mg if body weight was ≥5 kg at 5 to 6 months following the first dose (Day 150-180).

Arm type	Experimental
Investigational medicinal product name	Nirsevimab
Investigational medicinal product code	
Other name	MEDI8897
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants in the first year of life received the first dose of nirsevimab on Day 1 as a single, fixed IM dose of 50 mg if body weight was <5 kg or 100 mg if body weight was ≥5 kg. A second fixed IM dose of 50 mg was administered if body weight was <5 kg or 100 mg if body weight was ≥5 kg at 5 to 6 months following the first dose (Day 150-180).

Number of subjects in period 1	Nirsevimab 50 mg/100 mg
Started	33
Received study dose 1	33
Received study dose 2	32 ^[1]
Completed	33

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: One participant did not receive study dose 2 but did not discontinue the study, they

completed the study.

Baseline characteristics

Reporting groups

Reporting group title	Nirsevimab 50 mg/100 mg
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Reporting group description:

Participants in the first year of life received the first dose of nirsevimab on Day 1 as a single, fixed IM dose of 50 mg if body weight was <5 kg or 100 mg if body weight was ≥5 kg. A second fixed IM dose of 50 mg was administered if body weight was <5 kg or 100 mg if body weight was ≥5 kg at 5 to 6 months following the first dose (Day 150-180).

Reporting group values	Nirsevimab 50 mg/100 mg	Total	
Number of subjects	33	33	
Age categorical			
Units: Subjects			

Age Continuous			
Units: months			
arithmetic mean	2.32		
standard deviation	± 2.39	-	
Sex: Female, Male			
Units: participants			
Female	15	15	
Male	18	18	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	33	33	
Unknown or Not Reported	0	0	
Race/Ethnicity, Customized			
Units: Subjects			
Asian	33	33	

Subject analysis sets

Subject analysis set title	As-Treated Set 1
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Subject analysis set type	Full analysis
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Subject analysis set description:

The As-treated set 1 (ATS1) consists of all participants who receive at least 1 dose of IMP.

Subject analysis set title	As-Treated Set 2
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Subject analysis set type	Safety analysis
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Subject analysis set description:

The As-treated set 2 (ATS2) consists of all participants who receive the 2 doses of IMP.

Reporting group values	As-Treated Set 1	As-Treated Set 2	
Number of subjects	33	32	
Age categorical			
Units: Subjects			

Age Continuous Units: months arithmetic mean standard deviation	2.32 ± 2.39	2.32 ± 2.43	
Sex: Female, Male Units: participants			
Female	15	14	
Male	18	18	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	33	32	
Unknown or Not Reported	0	0	
Race/Ethnicity, Customized Units: Subjects			
Asian	33	32	

End points

End points reporting groups

Reporting group title	Nirsevimab 50 mg/100 mg
Reporting group description: Participants in the first year of life received the first dose of nirsevimab on Day 1 as a single, fixed IM dose of 50 mg if body weight was <5 kg or 100 mg if body weight was ≥5 kg. A second fixed IM dose of 50 mg was administered if body weight was <5 kg or 100 mg if body weight was ≥5 kg at 5 to 6 months following the first dose (Day 150-180).	
Subject analysis set title	As-Treated Set 1
Subject analysis set type	Full analysis
Subject analysis set description: The As-treated set 1 (ATS1) consists of all participants who receive at least 1 dose of IMP.	
Subject analysis set title	As-Treated Set 2
Subject analysis set type	Safety analysis
Subject analysis set description: The As-treated set 2 (ATS2) consists of all participants who receive the 2 doses of IMP.	

Primary: Number of Participants With Treatment-emergent Adverse Events (TEAEs), Treatment-emergent Serious Adverse Events (TESAEs), Adverse Events of Special Interest (AESIs), and new-onset Chronic Diseases (NOCs)

End point title	Number of Participants With Treatment-emergent Adverse Events (TEAEs), Treatment-emergent Serious Adverse Events (TESAEs), Adverse Events of Special Interest (AESIs), and new-onset Chronic Diseases (NOCs) ^[1]
End point description: An AE was development of any untoward medical occurrence in a participant or clinical study participant administered medicinal product and which did not necessarily have causal relationship with this treatment. TEAEs were AEs whose onset occurred after receiving nirsevimab through 360 days post second dose. An SAE was any AE that resulted in death, was immediately life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, was a congenital anomaly or birth defect or was an important medical event that might jeopardize the participant or may require medical treatment to prevent 1 of the outcomes listed above. AESIs were based on assessment by investigators following the administration of nirsevimab. An NOCD was a newly diagnosed medical condition of chronic, ongoing nature post administration of study drug.	
End point type	Primary
End point timeframe: From the first dose administration (Day 1) through 360 days post 2nd dose, study Day 511	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: One participant did not receive study dose 2 but did not discontinue the study, they completed the study.

End point values	Nirsevimab 50 mg/100 mg			
Subject group type	Reporting group			
Number of subjects analysed	32 ^[2]			
Units: participants				
TEAE	32			
TESAE	8			
AESI	0			
NOC	1			

Notes:

[2] - Based on the As-treated set 2 (N=32): all participants who receive the 2 doses of IMP.

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentrations of Nirsevimab

End point title	Serum Concentrations of Nirsevimab
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End point description:

Serum samples were collected at specified timepoints to evaluate concentrations of nirsevimab at selected time points.

End point type	Secondary
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End point timeframe:

Pre-dose Day 1, pre-dose Day 151, Day 181 post first-dose, Day 301 post first-dose, and Day 511 post first-dose

End point values	Nirsevimab 50 mg/100 mg			
Subject group type	Reporting group			
Number of subjects analysed	33 ^[3]			
Units: microgram/milliliter (mcg/mL)				
geometric mean (geometric coefficient of variation)				
Pre-dose Day 1	0 (± 0)			
Pre-dose Day 151	24.362 (± 24.639)			
Day 181	129.554 (± 19.090)			
Day 301	36.239 (± 48.154)			
Day 511	3.234 (± 111.784)			

Notes:

[3] - Participants in ATS1 with at least 1 quantifiable serum PK observation. (PK Analysis Set, N=33)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Anti-drug Antibody (ADA) Response to Nirsevimab

End point title	Number of Participants With Anti-drug Antibody (ADA) Response to Nirsevimab
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End point description:

Blood samples were analyzed for the presence of ADAs for nirsevimab using an appropriately validated bioanalytical method.

End point type	Secondary
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End point timeframe:

Pre-dose Day 1, pre-dose Day 151, Day 181 post first-dose, Day 301 post first-dose, and Day 511 post first-dose

End point values	Nirsevimab 50 mg/100 mg			
Subject group type	Reporting group			
Number of subjects analysed	32 ^[4]			
Units: participants				
Pre-dose Day 1	0			
Pre-dose Day 151	0			
Day 181	0			
Day 301	0			
Day 511	4			

Notes:

[4] - Participants in ATS2 with at least 1 non-missing ADA-sample post second dose. (ADA Set, N=32)

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Anti-respiratory Syncytial Virus (RSV) Neutralizing Antibody (nAb) Levels

End point title	Serum Anti-respiratory Syncytial Virus (RSV) Neutralizing Antibody (nAb) Levels
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End point description:

Blood samples were collected for the determination anti-RSV nAb in serum using an appropriately validated bioanalytical method.

End point type	Secondary
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End point timeframe:

Pre-dose Day 1, pre-dose Day 151, Day 181 post first-dose, Day 301 post first-dose, and Day 511 post first-dose

End point values	Nirsevimab 50 mg/100 mg			
Subject group type	Reporting group			
Number of subjects analysed	32 ^[5]			
Units: international units/mL				
geometric mean (geometric coefficient of variation)				
Pre-dose Day 1	254.6 (± 79.2)			
Pre-dose Day 151	8127.4 (± 18.8)			
Day 181	28552.2 (± 9.5)			
Day 301	11241.0 (± 24.8)			
Day 511	1302.1 (± 58.1)			

Notes:

[5] - Participants in ATS2 with at least 1 quantifiable serum nAb observation after the second dose (N=32)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From 1st dose through 360 days after 2nd dose

Adverse event reporting additional description:

Safety analyses and AE reporting is based on ATS2

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	28.0
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Reporting groups

Reporting group title	Nirsevimab
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Reporting group description: -

Serious adverse events	Nirsevimab		
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 32 (25.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural complication			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Infantile spasms			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Apnoea			

subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Asthma			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchitis viral			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metapneumovirus pneumonia			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia bacterial			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Viral sepsis			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis adenovirus			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
HCoV-OC43 infection			

subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Nirsevimab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	32 / 32 (100.00%)		
Vascular disorders			
Vascular insufficiency			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
General disorders and administration site conditions			
Injection site erythema			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Peripheral swelling			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	14 / 32 (43.75%)		
occurrences (all)	17		
Vaccination site erythema			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Immune system disorders			
Food allergy			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Allergy to animal			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Bacille Calmette-Guerin scar reactivation			

subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	3		
Nasal obstruction			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	3		
Pulmonary hypertension			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Rhinitis allergic			
subjects affected / exposed	5 / 32 (15.63%)		
occurrences (all)	5		
Rhinorrhoea			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	7		
Sputum increased			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Upper respiratory tract inflammation			
subjects affected / exposed	4 / 32 (12.50%)		
occurrences (all)	5		
Wheezing			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Bronchial hyperreactivity			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Asthma			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Cough			

subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Investigations Neutrophil count decreased subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Injury, poisoning and procedural complications Chillblains subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Immunisation reaction subjects affected / exposed occurrences (all)	6 / 32 (18.75%) 13		
Inflammation of wound subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Post procedural fever subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Post procedural oedema subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Radial head dislocation subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Scratch subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Thermal burn subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Arthropod sting subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2		
Arthropod bite			

subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Cardiac disorders Pulmonary valve stenosis subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Nervous system disorders Epilepsy subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Blood and lymphatic system disorders Anaemia neonatal subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Ear and labyrinth disorders Excessive cerumen production subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Eye disorders Eye pruritus subjects affected / exposed occurrences (all) Conjunctivitis allergic subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1 1 / 32 (3.13%) 1		
Gastrointestinal disorders Vomiting subjects affected / exposed occurrences (all) Haemorrhoids subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Constipation	3 / 32 (9.38%) 5 1 / 32 (3.13%) 1 9 / 32 (28.13%) 13		

subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	3		
Anal inflammation			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Enteritis			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Decubitus ulcer			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	2		
Dermatitis			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Dermatitis contact			
subjects affected / exposed	4 / 32 (12.50%)		
occurrences (all)	5		
Dry skin			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	5		
Eczema			
subjects affected / exposed	8 / 32 (25.00%)		
occurrences (all)	8		
Eczema asteatotic			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	4		
Eczema infantile			
subjects affected / exposed	4 / 32 (12.50%)		
occurrences (all)	4		
Miliaria			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	3		
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		

Urticaria subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2		
Dermatitis diaper subjects affected / exposed occurrences (all)	8 / 32 (25.00%) 13		
Dermatitis bullous subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Idiopathic urticaria subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Renal and urinary disorders Haematuria subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2		
Infections and infestations Gastroenteritis viral subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2		
Abscess limb subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Adenoviral conjunctivitis subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1		
Anal abscess subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2		
Bronchitis subjects affected / exposed occurrences (all)	4 / 32 (12.50%) 7		
Bronchitis viral			

subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Conjunctivitis			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	4		
Conjunctivitis bacterial			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Exanthema subitum			
subjects affected / exposed	4 / 32 (12.50%)		
occurrences (all)	5		
Gastroenteritis			
subjects affected / exposed	7 / 32 (21.88%)		
occurrences (all)	7		
Gastroenteritis norovirus			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Hand-foot-and-mouth disease			
subjects affected / exposed	12 / 32 (37.50%)		
occurrences (all)	14		
Hordeolum			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	3		
Impetigo			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Influenza			
subjects affected / exposed	4 / 32 (12.50%)		
occurrences (all)	4		
Lower respiratory tract infection			
subjects affected / exposed	5 / 32 (15.63%)		
occurrences (all)	13		
Lower respiratory tract infection viral			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Nasopharyngitis			

subjects affected / exposed	9 / 32 (28.13%)		
occurrences (all)	22		
Oral candidiasis			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Otitis externa			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Otitis externa bacterial			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Otitis media			
subjects affected / exposed	4 / 32 (12.50%)		
occurrences (all)	6		
Parainfluenzae viral bronchitis			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	3		
Paronychia			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Pharyngitis			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Respiratory syncytial virus infection			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	3		
Rhinitis			
subjects affected / exposed	5 / 32 (15.63%)		
occurrences (all)	6		
Upper respiratory tract infection			
subjects affected / exposed	25 / 32 (78.13%)		
occurrences (all)	65		
Upper respiratory tract infection bacterial			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		

Viral upper respiratory tract infection			
subjects affected / exposed	10 / 32 (31.25%)		
occurrences (all)	17		
Sinusitis			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Norovirus infection			
subjects affected / exposed	4 / 32 (12.50%)		
occurrences (all)	4		
Dacryocystitis			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
COVID-19			
subjects affected / exposed	5 / 32 (15.63%)		
occurrences (all)	5		
Suspected COVID-19			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Streptococcal infection			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Failure to thrive			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	1		
Feeding disorder			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences (all)	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

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

Not applicable

Notes: