



Clinical trial results:

A Phase 1, Open-Label, age-Descending, Dose-Finding Study to Evaluate the Safety, Tolerability, and Immunogenicity of Respiratory Syncytial Virus Prefusion F Subunit Vaccine (RSVpreF) in Children 2 to <18 Years of age

Summary

EudraCT number	2024-000422-17
Trial protocol	Outside EU/EEA
Global end of trial date	29 February 2024

Results information

Result version number	v1 (current)
This version publication date	28 November 2024
First version publication date	28 November 2024

Trial information

Trial identification

Sponsor protocol code	C3671016
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05900154
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-002795-PIP02-21
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	09 July 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 February 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the safety and tolerability of RSVpreF at each dose level in children 5 to less than (<) 18 years of age and children 2 to <5 years of age.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 June 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	United States: 127
Worldwide total number of subjects	127
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)	0
Children (2-11 years)	88
Adolescents (12-17 years)	39
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted in United States only, from 22 June 2023 to 29 February 2024. A total of 127 participants were enrolled and in receipt of RSVpreF.

Pre-assignment

Screening details:

Participants were divided into 2 age groups: 5 to <18 years and 2 to < 5 years. All participants received single dose of RSVpreF vaccine.

Period 1

Period 1 title	Period 1: Vaccination Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Healthy RSVpreF 120 micrograms (mcg)

Arm description:

Healthy participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

Arm type	Experimental
Investigational medicinal product name	RSVpreF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

120 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

Arm title	High Risk RSVpreF 120 mcg
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Arm description:

High risk participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

Arm type	Experimental
Investigational medicinal product name	RSVpreF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

120 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

Arm title	2 to < 5 Years RSVpreF 120 mcg
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Arm description:

Participants, 2 to < 5 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

Arm type	Experimental
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Investigational medicinal product name	RSVpreF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
120 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.	
Arm title	Healthy RSVpreF 60 mcg
Arm description:	
Healthy participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Arm type	Experimental
Investigational medicinal product name	RSVpreF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
60 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.	
Arm title	High Risk RSVpreF 60 mcg
Arm description:	
High risk participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Arm type	Experimental
Investigational medicinal product name	RSVpreF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
60 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.	
Arm title	2 to < 5 Years RSVpreF 60 mcg
Arm description:	
Participants, 2 to < 5 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Arm type	Experimental
Investigational medicinal product name	RSVpreF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
60 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.	

Number of subjects in period 1	Healthy RSVpreF 120 micrograms (mcg)	High Risk RSVpreF 120 mcg	2 to < 5 Years RSVpreF 120 mcg
Started	25	23	24
Completed	25	23	24

Number of subjects in period 1	Healthy RSVpreF 60 mcg	High Risk RSVpreF 60 mcg	2 to < 5 Years RSVpreF 60 mcg
Started	17	18	20
Completed	17	18	20

Period 2

Period 2 title	Period 2: Follow-Up Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Healthy RSVpreF 120 mcg

Arm description:

Healthy participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

Arm type	Experimental
Investigational medicinal product name	RSVpreF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

120 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

Arm title	High Risk RSVpreF 120 mcg
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Arm description:

High risk participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

Arm type	Experimental
Investigational medicinal product name	RSVpreF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

120 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

Arm title	2 to < 5 Years RSVpreF 120 mcg
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Arm description:

Participants, 2 to < 5 years of age received a single dose of 120 mcg RSVpreF as standard dose level

intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

Arm type	Experimental
Investigational medicinal product name	RSVpreF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

120 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

Arm title	Healthy RSVpreF 60 mcg
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Arm description:

Healthy participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

Arm type	Experimental
Investigational medicinal product name	RSVpreF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

60 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

Arm title	High Risk RSVpreF 60 mcg
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Arm description:

High risk participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

Arm type	Experimental
Investigational medicinal product name	RSVpreF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

60 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

Arm title	2 to < 5 Years RSVpreF 60 mcg
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Arm description:

Participants, 2 to < 5 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

Arm type	Experimental
Investigational medicinal product name	RSVpreF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

60 mcg of RSVpreF was administered intramuscularly as a single dose on Day 1.

Number of subjects in period 2	Healthy RSVpreF 120 mcg	High Risk RSVpreF 120 mcg	2 to < 5 Years RSVpreF 120 mcg
Started	25	23	24
Completed	24	21	23
Not completed	1	2	1
Lost to follow-up	1	2	1

Number of subjects in period 2	Healthy RSVpreF 60 mcg	High Risk RSVpreF 60 mcg	2 to < 5 Years RSVpreF 60 mcg
Started	17	18	20
Completed	17	17	19
Not completed	0	1	1
Lost to follow-up	-	1	1

Baseline characteristics

Reporting groups

Reporting group title	Healthy RSVpreF 120 micrograms (mcg)
Reporting group description: Healthy participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	High Risk RSVpreF 120 mcg
Reporting group description: High risk participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	2 to < 5 Years RSVpreF 120 mcg
Reporting group description: Participants, 2 to < 5 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	Healthy RSVpreF 60 mcg
Reporting group description: Healthy participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	High Risk RSVpreF 60 mcg
Reporting group description: High risk participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	2 to < 5 Years RSVpreF 60 mcg
Reporting group description: Participants, 2 to < 5 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	

Reporting group values	Healthy RSVpreF 120 micrograms (mcg)	High Risk RSVpreF 120 mcg	2 to < 5 Years RSVpreF 120 mcg
Number of subjects	25	23	24
Age Categorical Units: Participants			
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)	0	0	0
Children (2-11 years)	9	11	24
Adolescents (12-17 years)	16	12	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	12.56	11.04	3.00
standard deviation	± 4.55	± 3.50	± 0.78
Gender Categorical Units: Participants			
Female	15	11	13

Male	10	12	11
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Race			
Units: Subjects			
White	16	17	17
Black or African American	7	6	3
Asian	2	0	0
American Indian or Alaska Native	0	0	1
Multiracial	0	0	3
Ethnicity			
Units: Subjects			
Hispanic/Latino	5	0	1
Non-Hispanic/non-Latino	20	23	22
Not reported	0	0	1

Reporting group values	Healthy RSVpreF 60 mcg	High Risk RSVpreF 60 mcg	2 to < 5 Years RSVpreF 60 mcg
Number of subjects	17	18	20
Age Categorical			
Units: Participants			
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)	0	0	0
Children (2-11 years)	12	12	20
Adolescents (12-17 years)	5	6	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	9.53	9.61	3.20
standard deviation	± 3.57	± 3.40	± 0.77
Gender Categorical			
Units: Participants			
Female	5	7	7
Male	12	11	13
Race			
Units: Subjects			
White	13	9	15
Black or African American	2	6	4
Asian	0	0	0
American Indian or Alaska Native	0	0	0
Multiracial	2	3	1
Ethnicity			
Units: Subjects			
Hispanic/Latino	3	4	5
Non-Hispanic/non-Latino	14	13	15
Not reported	0	1	0

Reporting group values	Total		
Number of subjects	127		
Age Categorical			
Units: Participants			
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)	88		
Adolescents (12-17 years)	39		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender Categorical			
Units: Participants			
Female	58		
Male	69		
Race			
Units: Subjects			
White	87		
Black or African American	28		
Asian	2		
American Indian or Alaska Native	1		
Multiracial	9		
Ethnicity			
Units: Subjects			
Hispanic/Latino	18		
Non-Hispanic/non-Latino	107		
Not reported	2		

End points

End points reporting groups

Reporting group title	Healthy RSVpreF 120 micrograms (mcg)
Reporting group description: Healthy participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	High Risk RSVpreF 120 mcg
Reporting group description: High risk participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	2 to < 5 Years RSVpreF 120 mcg
Reporting group description: Participants, 2 to < 5 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	Healthy RSVpreF 60 mcg
Reporting group description: Healthy participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	High Risk RSVpreF 60 mcg
Reporting group description: High risk participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	2 to < 5 Years RSVpreF 60 mcg
Reporting group description: Participants, 2 to < 5 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	Healthy RSVpreF 120 mcg
Reporting group description: Healthy participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	High Risk RSVpreF 120 mcg
Reporting group description: High risk participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	2 to < 5 Years RSVpreF 120 mcg
Reporting group description: Participants, 2 to < 5 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	Healthy RSVpreF 60 mcg
Reporting group description: Healthy participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	High Risk RSVpreF 60 mcg
Reporting group description: High risk participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	
Reporting group title	2 to < 5 Years RSVpreF 60 mcg
Reporting group description: Participants, 2 to < 5 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.	

Primary: Percentage of Participants With Local Reactions Within 7 Days After Vaccination

End point title	Percentage of Participants With Local Reactions Within 7 Days After Vaccination ^[1]
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End point description:

Local reactions were collected in the electronic diary (e-diary) from Day 1 through Day 7 after vaccination. Local reactions included redness, swelling and pain at injection site. For participants greater than or equal to (\geq) 2 years to <12 years of age, redness and swelling were graded as mild: 0.5 to 2.0 centimeter (cm), moderate: >2.0 to 7.0 cm, and severe: >7 cm; for participants ≥ 12 years of age, mild: >2.0 to 5.0 cm, moderate: >5.0 to 10.0 cm, and severe: >10 cm. Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), and severe (prevented daily activity). Percentage of participants reporting local reactions at injection site and associated 2-sided 95% confidence interval (CI) based on Clopper and Pearson method was presented in this endpoint. Safety population included all enrolled participants who received study intervention.

End point type	Primary
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End point timeframe:

Within 7 days after Vaccination

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: Only descriptive data was planned to be analyzed

End point values	Healthy RSVpreF 120 micrograms (mcg)	High Risk RSVpreF 120 mcg	2 to <5 Years RSVpreF 120 mcg	Healthy RSVpreF 60 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	23	24	17
Units: Percentage of participants				
number (confidence interval 95%)				
Pain at injection site: Mild	36.0 (18.0 to 57.5)	39.1 (19.7 to 61.5)	8.3 (1.0 to 27.0)	35.3 (14.2 to 61.7)
Pain at injection site: Moderate	8.0 (1.0 to 26.0)	8.7 (1.1 to 28.0)	0 (0.0 to 14.2)	5.9 (0.1 to 28.7)
Pain at injection site: Severe	4.0 (0.1 to 20.4)	0 (0.0 to 14.8)	0 (0.0 to 14.2)	0 (0.0 to 19.5)
Redness: Mild	12.0 (2.5 to 31.2)	4.3 (0.1 to 21.9)	12.5 (2.7 to 32.4)	0 (0.0 to 19.5)
Redness: Moderate	12.0 (2.5 to 31.2)	4.3 (0.1 to 21.9)	0 (0.0 to 14.2)	5.9 (0.1 to 28.7)
Redness: Severe	0 (0.0 to 13.7)	0 (0.0 to 14.8)	0 (0.0 to 14.2)	0 (0.0 to 19.5)
Swelling: Mild	4.0 (0.1 to 20.4)	0 (0.0 to 14.8)	4.2 (0.1 to 21.1)	0 (0.0 to 19.5)
Swelling: Moderate	8.0 (1.0 to 26.0)	8.7 (1.1 to 28.0)	0 (0.0 to 14.2)	5.9 (0.1 to 28.7)
Swelling: Severe	0 (0.0 to 13.7)	0 (0.0 to 14.8)	0 (0.0 to 14.2)	0 (0.0 to 19.5)

End point values	High Risk RSVpreF 60 mcg	2 to <5 Years RSVpreF 60 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	20		
Units: Percentage of participants				
number (confidence interval 95%)				
Pain at injection site: Mild	33.3 (13.3 to 59.0)	15.0 (3.2 to 37.9)		

Pain at injection site: Moderate	22.2 (6.4 to 47.6)	0 (0.0 to 16.8)		
Pain at injection site: Severe	0 (0.0 to 18.5)	0 (0.0 to 16.8)		
Redness: Mild	11.1 (1.4 to 34.7)	5.0 (0.1 to 24.9)		
Redness: Moderate	0 (0.0 to 18.5)	0 (0.0 to 16.8)		
Redness: Severe	0 (0.0 to 18.5)	0 (0.0 to 16.8)		
Swelling: Mild	11.1 (1.4 to 34.7)	0 (0.0 to 16.8)		
Swelling: Moderate	11.1 (1.4 to 34.7)	5.0 (0.1 to 24.9)		
Swelling: Severe	0 (0.0 to 18.5)	0 (0.0 to 16.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Systemic Events Within 7 Days After Vaccination

End point title	Percentage of Participants With Systemic Events Within 7 Days After Vaccination ^[2]
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End point description:

Systemic events included fever, fatigue, headache, vomiting, diarrhea, muscle pain and joint pain and were recorded by participants using e-diary. Fever: oral temperature ≥ 38.0 degree Celsius (deg C) and categorised as ≥ 38.0 to 38.4 deg C (mild), >38.4 to 38.9 deg C (moderate), and >38.9 to 40.0 deg C (severe). Fatigue, headache, muscle pain and joint pain were graded as mild (did not interfere with activity), moderate (some interference with activity), and severe (prevented daily routine activity). Vomiting was graded mild: 1-2 times in 24 hours (h), moderate: >2 times in 24h, and severe: required intravenous hydration. Diarrhea was graded mild: 2-3 loose stools in 24h, moderate: 4-5 loose stools in 24h and severe: 6 or more loose stools in 24h. Percentage of participants with systemic events within 7 days after vaccination and associated 2-sided 95% CI based on Clopper and Pearson method was presented. Safety population = all enrolled participants who received study intervention.

End point type	Primary
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End point timeframe:

Within 7 days after Vaccination

Notes:

[2] - 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: Only descriptive data was planned to be analyzed

End point values	Healthy RSVpreF 120 micrograms (mcg)	High Risk RSVpreF 120 mcg	2 to < 5 Years RSVpreF 120 mcg	Healthy RSVpreF 60 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	23	24	17
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: Mild	0 (0.0 to 13.7)	4.3 (0.1 to 21.9)	4.2 (0.1 to 21.1)	0 (0.0 to 19.5)
Fever: Moderate	0 (0.0 to 13.7)	0 (0.0 to 14.8)	0 (0.0 to 14.2)	0 (0.0 to 19.5)
Fever: Severe	0 (0.0 to 13.7)	0 (0.0 to 14.8)	0 (0.0 to 14.2)	5.9 (0.1 to 28.7)
Fatigue: Mild	20.0 (6.8 to 40.7)	21.7 (7.5 to 43.7)	20.8 (7.1 to 42.2)	41.2 (18.4 to 67.1)

Fatigue: Moderate	12.0 (2.5 to 31.2)	21.7 (7.5 to 43.7)	8.3 (1.0 to 27.0)	5.9 (0.1 to 28.7)
Fatigue: Severe	0 (0.0 to 13.7)	0 (0.0 to 14.8)	0 (0.0 to 14.2)	0 (0.0 to 19.5)
Headache: Mild	16.0 (4.5 to 36.1)	26.1 (10.2 to 48.4)	0 (0.0 to 14.2)	29.4 (10.3 to 56.0)
Headache: Moderate	12.0 (2.5 to 31.2)	8.7 (1.1 to 28.0)	4.2 (0.1 to 21.1)	11.8 (1.5 to 36.4)
Headache: Severe	0 (0.0 to 13.7)	0 (0.0 to 14.8)	0 (0.0 to 14.2)	0 (0.0 to 19.5)
Muscle pain: Mild	16.0 (4.5 to 36.1)	21.7 (7.5 to 43.7)	0 (0.0 to 14.2)	23.5 (6.8 to 49.9)
Muscle pain: Moderate	4.0 (0.1 to 20.4)	17.4 (5.0 to 38.8)	0 (0.0 to 14.2)	0 (0.0 to 19.5)
Muscle pain: Severe	0 (0.0 to 13.7)	0 (0.0 to 14.8)	0 (0.0 to 14.2)	0 (0.0 to 19.5)
Joint pain: Mild	4.0 (0.1 to 20.4)	4.3 (0.1 to 21.9)	0 (0.0 to 14.2)	0 (0.0 to 19.5)
Joint pain: Moderate	4.0 (0.1 to 20.4)	0 (0.0 to 14.8)	0 (0.0 to 14.2)	0 (0.0 to 19.5)
Joint pain: Severe	0 (0.0 to 13.7)	0 (0.0 to 14.8)	0 (0.0 to 14.2)	0 (0.0 to 19.5)
Vomiting: Mild	0 (0.0 to 13.7)	0 (0.0 to 14.8)	0 (0.0 to 14.2)	5.9 (0.1 to 28.7)
Vomiting: Moderate	0 (0.0 to 13.7)	0 (0.0 to 14.8)	0 (0.0 to 14.2)	0 (0.0 to 19.5)
Vomiting: Severe	0 (0.0 to 13.7)	0 (0.0 to 14.8)	0 (0.0 to 14.2)	0 (0.0 to 19.5)
Diarrhea: Mild	4.0 (0.1 to 20.4)	8.7 (1.1 to 28.0)	4.2 (0.1 to 21.1)	0 (0.0 to 19.5)
Diarrhea: Moderate	0 (0.0 to 13.7)	0 (0.0 to 14.8)	8.3 (1.0 to 27.0)	0 (0.0 to 19.5)
Diarrhea: Severe	0 (0.0 to 13.7)	0 (0.0 to 14.8)	0 (0.0 to 14.2)	0 (0.0 to 19.5)

End point values	High Risk RSVpreF 60 mcg	2 to < 5 Years RSVpreF 60 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	20		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: Mild	0 (0.0 to 18.5)	5.0 (0.1 to 24.9)		
Fever: Moderate	5.6 (0.1 to 27.3)	0 (0.0 to 16.8)		
Fever: Severe	5.6 (0.1 to 27.3)	0 (0.0 to 16.8)		
Fatigue: Mild	16.7 (3.6 to 41.4)	30.0 (11.9 to 54.3)		
Fatigue: Moderate	33.3 (13.3 to 59.0)	5.0 (0.1 to 24.9)		
Fatigue: Severe	0 (0.0 to 18.5)	0 (0.0 to 16.8)		
Headache: Mild	16.7 (3.6 to 41.4)	0 (0.0 to 16.8)		
Headache: Moderate	16.7 (3.6 to 41.4)	0 (0.0 to 16.8)		
Headache: Severe	0 (0.0 to 18.5)	0 (0.0 to 16.8)		
Muscle pain: Mild	33.3 (13.3 to 59.0)	0 (0.0 to 16.8)		
Muscle pain: Moderate	5.6 (0.1 to 27.3)	0 (0.0 to 16.8)		
Muscle pain: Severe	0 (0.0 to 18.5)	0 (0.0 to 16.8)		

Joint pain: Mild	11.1 (1.4 to 34.7)	0 (0.0 to 16.8)		
Joint pain: Moderate	0 (0.0 to 18.5)	0 (0.0 to 16.8)		
Joint pain: Severe	0 (0.0 to 18.5)	0 (0.0 to 16.8)		
Vomiting: Mild	5.6 (0.1 to 27.3)	10.0 (1.2 to 31.7)		
Vomiting: Moderate	0 (0.0 to 18.5)	0 (0.0 to 16.8)		
Vomiting: Severe	0 (0.0 to 18.5)	0 (0.0 to 16.8)		
Diarrhea: Mild	5.6 (0.1 to 27.3)	0 (0.0 to 16.8)		
Diarrhea: Moderate	0 (0.0 to 18.5)	0 (0.0 to 16.8)		
Diarrhea: Severe	0 (0.0 to 18.5)	0 (0.0 to 16.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Adverse Events (AEs) Within 1 Month After Vaccination

End point title	Percentage of Participants With Adverse Events (AEs) Within 1 Month After Vaccination ^[3]
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End point description:

AE was defined as any untoward medical occurrence in clinical study participant, temporally associated with use of study intervention, whether or not considered related to study intervention. AEs included serious and non-serious AE. Serious AEs (SAEs) were defined as AE that, at any dose: resulted in death; life-threatening; required inpatient hospitalisation/prolongation of existing hospitalisation; resulted in persistent disability/incapacity; was congenital anomaly/birth defect; was suspected transmission via Pfizer product of infectious agent, pathogenic or nonpathogenic or was considered to be important medical event. Percentage of participants reporting AEs within 1 month after Vaccination were reported. Exact 2-sided CI was calculated using Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e., excluding local reactions and systemic events) were reported. Safety population included all enrolled participants who received study intervention.

End point type	Primary
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End point timeframe:

Within 1 month after Vaccination

Notes:

[3] - 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: Only descriptive data was planned to be analyzed

End point values	Healthy RSVpreF 120 micrograms (mcg)	High Risk RSVpreF 120 mcg	2 to < 5 Years RSVpreF 120 mcg	Healthy RSVpreF 60 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	23	24	17
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 13.7)	17.4 (5.0 to 38.8)	12.5 (2.7 to 32.4)	0 (0.0 to 19.5)

End point values	High Risk RSVpreF 60 mcg	2 to < 5 Years RSVpreF 60 mcg		
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Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	20		
Units: Percentage of participants				
number (confidence interval 95%)	27.8 (9.7 to 53.5)	15.0 (3.2 to 37.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Serious Adverse Events (SAEs) Throughout the Study

End point title	Percentage of Participants With Serious Adverse Events (SAEs) Throughout the Study ^[4]
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End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. SAEs were defined as an AE that, at any dose: resulted in death; was life-threatening; required inpatient hospitalisation or prolongation of existing hospitalisation; resulted in persistent disability/incapacity; was a congenital anomaly/birth defect; was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or nonpathogenic or that was considered to be an important medical event. Percentage of participants with SAEs and the associated 2-sided 95% CI based on the Clopper and Pearson method was presented. Percentage of participants reporting SAEs within 1 month after Vaccination were reported in this endpoint. Safety population included all enrolled participants who received study intervention.

End point type	Primary
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End point timeframe:

From Day 1 up to 6-month follow-up visit after Day 1

Notes:

[4] - 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: Only descriptive data was planned to be analyzed

End point values	Healthy RSVpreF 120 micrograms (mcg)	High Risk RSVpreF 120 mcg	2 to < 5 Years RSVpreF 120 mcg	Healthy RSVpreF 60 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	23	24	17
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 13.7)	4.3 (0.1 to 21.9)	0 (0.0 to 14.2)	0 (0.0 to 19.5)

End point values	High Risk RSVpreF 60 mcg	2 to < 5 Years RSVpreF 60 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	20		
Units: Percentage of participants				
number (confidence interval 95%)	5.6 (0.1 to 27.3)	0 (0.0 to 16.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Reporting Newly Diagnosed Chronic Medical Condition (NDCMCs) Throughout the Study

End point title	Percentage of Participants Reporting Newly Diagnosed Chronic Medical Condition (NDCMCs) Throughout the Study ^[5]
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End point description:

An NDCMC was defined as a disease or medical condition, which was not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. Percentage of participants reporting NDCMC throughout the study was reported in this endpoint. Safety population included all enrolled participants who received study intervention.

End point type	Primary
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End point timeframe:

From Day 1 up to 6-month follow-up visit after Day 1

Notes:

[5] - 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: Only descriptive data was planned to be analyzed

End point values	Healthy RSVpreF 120 micrograms (mcg)	High Risk RSVpreF 120 mcg	2 to < 5 Years RSVpreF 120 mcg	Healthy RSVpreF 60 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	23	24	17
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 13.7)	0 (0.0 to 14.8)	0 (0.0 to 14.2)	0 (0.0 to 19.5)

End point values	High Risk RSVpreF 60 mcg	2 to < 5 Years RSVpreF 60 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	20		
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 18.5)	0 (0.0 to 16.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titer of the Neutralising Titers for RSV A and RSV B

Before Vaccination and 1 Month After Vaccination

End point title	Geometric Mean Titer of the Neutralising Titers for RSV A and RSV B Before Vaccination and 1 Month After Vaccination
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End point description:

Geometric mean titer (GMT) of neutralising titers of respiratory syncytial virus subgroup A and respiratory syncytial virus subgroup B (RSV A and RSV B) before vaccination and 1 month (M) after vaccination were reported in this endpoint. Assay results below the lower limit of quantification (LLOQ) were set to 0.5*LLOQ. The LLOQ for each neutralisation titer were: RSV A 50% = 242, RSV B 50% = 99. GMTs and corresponding 2-sided CIs were calculated by exponentiating mean logarithm of titers and corresponding CIs (based on Student's t distribution). Evaluable immunogenicity population (EIP) included all eligible participants who received the study intervention; had 1-month postvaccination blood collection 27 through 42 days after vaccination; had at least 1 valid and determinate assay result 1 month after vaccination; had no major protocol violations from vaccination through the 1-month postvaccination blood draw. Here, 'n' signifies participants evaluable for the specified rows.

End point type	Secondary
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End point timeframe:

Before vaccination and 1 month after vaccination

End point values	Healthy RSVpreF 120 mcg	High Risk RSVpreF 120 mcg	2 to < 5 Years RSVpreF 120 mcg	Healthy RSVpreF 60 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	21	24	15
Units: Titer				
geometric mean (confidence interval 95%)				
RSV A: Before vaccination (n=24,20,24,15,18,20)	1168 (706 to 1932)	2003 (1421 to 2823)	529 (335 to 835)	916 (653 to 1285)
RSV A: 1 M after vaccination (n=24,21,24,15,18,20)	27862 (21493 to 36119)	35503 (26876 to 46900)	26146 (13301 to 51396)	25341 (15394 to 41715)
RSV B: Before vaccination (n=24,20,24,15,18,20)	1206 (717 to 2027)	1905 (1238 to 2930)	391 (231 to 661)	965 (668 to 1393)
RSV B: 1 M after vaccination (n=24,21,24,15,18,20)	30251 (21607 to 42355)	29019 (18786 to 44827)	16504 (8267 to 32948)	33351 (23565 to 47202)
RSVA/RSVB: Before vaccination (n=24,20,24,15,18,20)	1187 (741 to 1900)	1953 (1353 to 2820)	455 (285 to 727)	940 (698 to 1268)
A/B: 1 M after vaccination (n=24,21,24,15,18,20)	29032 (22267 to 37853)	32098 (23148 to 44509)	20773 (10644 to 40543)	29071 (19691 to 42920)

End point values	High Risk RSVpreF 60 mcg	2 to < 5 Years RSVpreF 60 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	20		
Units: Titer				
geometric mean (confidence interval 95%)				
RSV A: Before vaccination (n=24,20,24,15,18,20)	1667 (1035 to 2684)	561 (309 to 1016)		
RSV A: 1 M after vaccination (n=24,21,24,15,18,20)	24053 (17440 to 33173)	11004 (4287 to 28245)		
RSV B: Before vaccination (n=24,20,24,15,18,20)	1760 (947 to 3272)	499 (258 to 967)		

RSV B:1 M after vaccination(n=24,21,24,15,18,20)	31174 (21756 to 44668)	10659 (3526 to 32228)		
RSVA/RSVB: Before vaccination(n=24,20,24,15,18,20)	1713 (1017 to 2884)	529 (295 to 950)		
A/B: 1 M after vaccination (n=24,21,24,15,18,20)	27383 (20364 to 36820)	10830 (3928 to 29860)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rise (GMFR) of the NTs for RSV A and RSV B From Before Vaccination to 1 Month After Vaccination

End point title	Geometric Mean Fold Rise (GMFR) of the NTs for RSV A and RSV B From Before Vaccination to 1 Month After Vaccination
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End point description:

GMFR of neutralising titers of RSV A and RSV B from before vaccination to 1 month after vaccination were reported in this endpoint. GMFR and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the fold rises and the corresponding CIs (based on the Student's t distribution). Evaluable immunogenicity population included all eligible participants who received the study intervention; had 1-month postvaccination blood collection 27 through 42 days after vaccination; had at least 1 valid and determinate assay result 1 month after vaccination; had no major protocol violations from vaccination through the 1-month postvaccination blood draw.

End point type	Secondary
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End point timeframe:

From before vaccination to 1 month after vaccination

End point values	Healthy RSVpreF 120 micrograms (mcg)	High Risk RSVpreF 120 mcg	2 to < 5 Years RSVpreF 120 mcg	Healthy RSVpreF 60 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	20	24	15
Units: Fold rise				
geometric mean (confidence interval 95%)				
RSV A	21.9 (14.46 to 33.08)	18.6 (13.03 to 26.55)	42.8 (23.41 to 78.16)	27.7 (17.81 to 42.93)
RSV B	24.4 (15.53 to 38.26)	16.3 (9.91 to 26.83)	39.8 (22.96 to 69.08)	34.6 (21.63 to 55.23)
RSV A/ RSV B	23.1 (15.17 to 35.16)	17.4 (11.73 to 25.85)	41.3 (23.49 to 72.51)	30.9 (19.99 to 47.81)

End point values	High Risk RSVpreF 60 mcg	2 to < 5 Years RSVpreF 60 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	20		
Units: Fold rise				
geometric mean (confidence interval				

95%)				
RSV A	13.9 (8.75 to 22.03)	17.7 (9.02 to 34.67)		
RSV B	17.0 (9.25 to 31.40)	20.6 (10.00 to 42.50)		
RSV A/ RSV B	15.4 (9.12 to 25.94)	19.1 (9.61 to 37.96)		

Statistical analyses

No statistical analyses for this end point

Secondary: Median Frequencies of RSV F Antigen-Specific Cluster of Differentiation 4 (CD4+) Thymus-Derived Lymphocytes (T) Cells Expressing Interferon (IFN) Gamma and Interleukin-4 (IL-4) Before Vaccination and 1 Month After Vaccination

End point title	Median Frequencies of RSV F Antigen-Specific Cluster of Differentiation 4 (CD4+) Thymus-Derived Lymphocytes (T) Cells Expressing Interferon (IFN) Gamma and Interleukin-4 (IL-4) Before Vaccination and 1 Month After Vaccination
End point description:	Median frequencies of RSV F antigen-specific CD4+ T cells expressing IFN gamma and IL-4 before vaccination (vax) and 1M after vax were reported in this endpoint. RSV F enzyme-linked immune absorbent spot assay (ELISpot) limit of detection (LOD) values were IFN gamma=20 spot forming cell (SFC) per million peripheral blood mononuclear cell (PBMCs) and IL-4= 4 SFC/million PBMCs. Assay results below LOD=0.5*LOD for analysis, with exception of calculating fold-rise when before vax assay value was below LOD but corresponding after vax assay value was at LOD or above, where LOD was set for before vaccination. EIP= all eligible participants who received intervention; had 1-M postvaccination blood collection 27 to 42 days after vax; had at least 1 valid, determinate assay result 1 M after vax; had no major protocol violations from vax through 1M postvaccination blood draw. 'Number of Subjects Analysed'=participants evaluable for this endpoint and 'n'=participants evaluable for specified rows.
End point type	Secondary
End point timeframe:	Before vaccination and 1 Month after vaccination

End point values	Healthy RSVpreF 120 micrograms (mcg)	High Risk RSVpreF 120 mcg	2 to < 5 Years RSVpreF 120 mcg	Healthy RSVpreF 60 mcg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	21	22	15
Units: SFC/million PBMCs				
median (full range (min-max))				
INF gamma before vax (n=23, 19, 22, 14, 17, 17)	47 (10 to 241)	60 (10 to 193)	10 (10 to 67)	53 (10 to 277)
INF gamma 1 month after vax (n=22,21,21,15,18,17)	255 (10 to 829)	293 (10 to 1339)	61 (10 to 257)	244 (23 to 1027)
IL-4 before vax (n=23, 19, 22, 14, 17, 17)	2 (2 to 2)	2 (2 to 11)	2 (2 to 2)	2 (2 to 4)
IL-4 1 month after vax (n= 22, 21, 21, 15, 18, 17)	2 (2 to 16)	4 (2 to 28)	2 (2 to 7)	2 (2 to 24)

End point values	High Risk RSVpreF 60 mcg	2 to < 5 Years RSVpreF 60 mcg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	17		
Units: SFC/million PBMCs				
median (full range (min-max))				
INF gamma before vax (n=23, 19, 22, 14, 17, 17)	41 (10 to 336)	10 (10 to 79)		
INF gamma 1 month after vax (n=22,21,21,15,18,17)	187 (10 to 780)	45 (10 to 184)		
IL-4 before vax (n=23, 19, 22, 14, 17, 17)	2 (2 to 5)	2 (2 to 4)		
IL-4 1 month after vax (n= 22, 21, 21, 15, 18, 17)	2 (2 to 15)	2 (2 to 13)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Local reactions and systemic events: Within 7 days after vaccination. SAEs and other AEs: up to 6-month follow-up visit after Day 1

Adverse event reporting additional description:

Same event may appear as both non-SAE and SAE but what is presented are distinct events. An event may be categorised as serious in one participant and nonserious in another participant or one participant may have experienced both serious and non-serious event. Safety population included all enrolled participants who received study intervention.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.1
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Reporting groups

Reporting group title	Healthy RSVpreF 120 mcg
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Reporting group description:

Healthy participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

Reporting group title	High Risk RSVpreF 120 mcg
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Reporting group description:

High risk participants, 5 to < 18 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

Reporting group title	2 to < 5 Years RSVpreF 60 mcg
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Reporting group description:

Participants, 2 to < 5 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

Reporting group title	Healthy RSVpreF 60 mcg
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Reporting group description:

Healthy participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

Reporting group title	High Risk RSVpreF 60 mcg
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Reporting group description:

High risk participants, 5 to < 18 years of age received a single dose of 60 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

Reporting group title	2 to < 5 Years RSVpreF 120 mcg
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Reporting group description:

Participants, 2 to < 5 years of age received a single dose of 120 mcg RSVpreF as standard dose level intramuscularly into the deltoid muscle (Vaccination 1) on Day 1.

Serious adverse events	Healthy RSVpreF 120 mcg	High Risk RSVpreF 120 mcg	2 to < 5 Years RSVpreF 60 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 20 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Immune system disorders			
Food allergy			

subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 20 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 20 (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	Healthy RSVpreF 60 mcg	High Risk RSVpreF 60 mcg	2 to < 5 Years RSVpreF 120 mcg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 17 (0.00%)	1 / 18 (5.56%)	0 / 24 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 17 (0.00%)	0 / 18 (0.00%)	0 / 24 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 17 (0.00%)	1 / 18 (5.56%)	0 / 24 (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

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

Non-serious adverse events	Healthy RSVpreF 120 mcg	High Risk RSVpreF 120 mcg	2 to < 5 Years RSVpreF 60 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 25 (68.00%)	15 / 23 (65.22%)	13 / 20 (65.00%)
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Headache (HEADACHE) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	7 / 25 (28.00%) 7	8 / 23 (34.78%) 8	0 / 20 (0.00%) 0
Syncope subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 20 (0.00%) 0
General disorders and administration site conditions Axillary pain subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 20 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	2 / 23 (8.70%) 2	0 / 20 (0.00%) 0
Fatigue (FATIGUE) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	8 / 25 (32.00%) 8	10 / 23 (43.48%) 10	7 / 20 (35.00%) 7
Injection site erythema subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	2 / 23 (8.70%) 2	0 / 20 (0.00%) 0
Injection site pain subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	3 / 23 (13.04%) 3	0 / 20 (0.00%) 0
Injection site pain (PAIN AT INJECTION SITE) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	12 / 25 (48.00%) 12	11 / 23 (47.83%) 11	3 / 20 (15.00%) 3
Injection site swelling subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 20 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	1 / 20 (5.00%) 1
Pyrexia (FEVER)			

alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 23 (4.35%) 1	1 / 20 (5.00%) 1
Swelling (SWELLING) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 3	2 / 23 (8.70%) 2	1 / 20 (5.00%) 1
Immune system disorders Food allergy subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 20 (0.00%) 0
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 20 (0.00%) 0
Diarrhoea (DIARRHEA) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	1 / 25 (4.00%) 1	2 / 23 (8.70%) 2	0 / 20 (0.00%) 0
Vomiting (VOMITING) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	2 / 20 (10.00%) 2
Skin and subcutaneous tissue disorders Erythema (REDNESS) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	6 / 25 (24.00%) 6	2 / 23 (8.70%) 2	1 / 20 (5.00%) 1
Musculoskeletal and connective tissue disorders Arthralgia (JOINT PAIN) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	1 / 23 (4.35%) 1	0 / 20 (0.00%) 0
Myalgia			

subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 20 (0.00%) 0
Myalgia (MUSCLE PAIN) alternative assessment type: Systematic			
subjects affected / exposed occurrences (all)	5 / 25 (20.00%) 5	9 / 23 (39.13%) 9	0 / 20 (0.00%) 0
Infections and infestations			
Gastroenteritis viral			
subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 20 (0.00%) 0
COVID-19			
subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 20 (0.00%) 0
Viral infection			
subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	1 / 20 (5.00%) 1

Non-serious adverse events	Healthy RSVpreF 60 mcg	High Risk RSVpreF 60 mcg	2 to < 5 Years RSVpreF 120 mcg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 17 (70.59%)	14 / 18 (77.78%)	9 / 24 (37.50%)
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	1 / 18 (5.56%) 1	0 / 24 (0.00%) 0
Nervous system disorders			
Headache (HEADACHE) alternative assessment type: Systematic			
subjects affected / exposed occurrences (all)	7 / 17 (41.18%) 7	6 / 18 (33.33%) 6	1 / 24 (4.17%) 1
Syncope			
subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	1 / 18 (5.56%) 1	0 / 24 (0.00%) 0
General disorders and administration site conditions			
Axillary pain			
subjects affected / exposed occurrences (all)	0 / 17 (0.00%) 0	1 / 18 (5.56%) 1	0 / 24 (0.00%) 0

Fatigue			
subjects affected / exposed	0 / 17 (0.00%)	1 / 18 (5.56%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Fatigue (FATIGUE)			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 17 (47.06%)	9 / 18 (50.00%)	7 / 24 (29.17%)
occurrences (all)	8	9	7
Injection site erythema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 18 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	1 / 17 (5.88%)	1 / 18 (5.56%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Injection site pain (PAIN AT INJECTION SITE)			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 17 (41.18%)	10 / 18 (55.56%)	2 / 24 (8.33%)
occurrences (all)	7	10	2
Injection site swelling			
subjects affected / exposed	0 / 17 (0.00%)	1 / 18 (5.56%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 18 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 17 (5.88%)	2 / 18 (11.11%)	1 / 24 (4.17%)
occurrences (all)	1	2	1
Swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 17 (5.88%)	4 / 18 (22.22%)	1 / 24 (4.17%)
occurrences (all)	1	4	1
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 17 (0.00%)	1 / 18 (5.56%)	0 / 24 (0.00%)
occurrences (all)	0	1	0

Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all) Diarrhoea (DIARRHEA) alternative assessment type: Systematic subjects affected / exposed occurrences (all) Vomiting (VOMITING) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 17 (0.00%)	1 / 18 (5.56%)	0 / 24 (0.00%)
	0	1	0
	0 / 17 (0.00%)	1 / 18 (5.56%)	3 / 24 (12.50%)
	0	1	3
	1 / 17 (5.88%)	1 / 18 (5.56%)	0 / 24 (0.00%)
	1	1	0
Skin and subcutaneous tissue disorders Erythema (REDNESS) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	1 / 17 (5.88%)	2 / 18 (11.11%)	3 / 24 (12.50%)
	1	2	3
Musculoskeletal and connective tissue disorders Arthralgia (JOINT PAIN) alternative assessment type: Systematic subjects affected / exposed occurrences (all) Myalgia subjects affected / exposed occurrences (all) Myalgia (MUSCLE PAIN) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 17 (0.00%)	2 / 18 (11.11%)	0 / 24 (0.00%)
	0	2	0
	1 / 17 (5.88%)	0 / 18 (0.00%)	0 / 24 (0.00%)
	1	0	0
	4 / 17 (23.53%)	7 / 18 (38.89%)	0 / 24 (0.00%)
	4	7	0
Infections and infestations Gastroenteritis viral subjects affected / exposed occurrences (all) COVID-19 subjects affected / exposed occurrences (all)	0 / 17 (0.00%)	1 / 18 (5.56%)	0 / 24 (0.00%)
	0	1	0
	0 / 17 (0.00%)	1 / 18 (5.56%)	0 / 24 (0.00%)
	0	1	0

Viral infection			
subjects affected / exposed	0 / 17 (0.00%)	1 / 18 (5.56%)	1 / 24 (4.17%)
occurrences (all)	0	1	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 February 2024	Added the clinicaltrials.gov reference and sponsor legal address to the title page. Removed Phase 2/3 content.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
28 July 2023	The study was interrupted due to reports of study intervention dosing errors at some investigational sites. The study was resumed after the site staff were retrained in preparation of study intervention.	08 August 2023

Notes:

Limitations and caveats

None reported