Clinical trial results:
A phase 3, randomized, double-blind, multi-country study to evaluate consistency, safety, and reactogenicity of 3 lots of RSVPreF3 OA investigational vaccine administrated as a single dose in adults aged 60 years and above.

Summary

EudraCT number	2021-002225-18
Trial protocol	SE
Global end of trial date	30 June 2022

Results information

Result version number	v1 (current)
This version publication date	15 February 2023
First version publication date	15 February 2023

Trial information

Trial identification

Sponsor protocol code	217131

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05059301
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	GSK Response Center, GlaxoSmithKline, 20 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 20 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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 September 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 June 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the lot to lot consistency of 3 lots of the RSVPreF3 OA investigational vaccine in terms of immunogenicity.

Protection of trial subjects:

Study participants must be observed closely for at least 30 minutes after the administration of the study intervention. Appropriate medical treatment must be readily available during the observation period in case of anaphylaxis.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2021
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	Canada: 322
Country: Number of subjects enrolled	Sweden: 254
Country: Number of subjects enrolled	United States: 194
Worldwide total number of subjects	770
EEA total number of subjects	254

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	180
From 65 to 84 years	573

85 years and over	17

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Out of 770 participants enrolled 757 received the study vaccine and were included in the Exposed Set.

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, Carer, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	RSV OA_Lot 1

Arm description:

Participants received 1 dose of a combination of the RSVPreF3 antigen Lot 1 and AS01E adjuvant Lot A at Day 1 and were followed up until the study end (Month 6).

Arm type	Experimental
Investigational medicinal product name	RSVPreF3 OA investigational vaccine - Lot 1 + AS01E adjuvant - Lot A
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose of RSVPreF3 Lot 1 vaccine reconstituted with 0.5 mL AS01E Lot A adjuvant administered intramuscularly in the deltoid region of the non-dominant arm.

Arm title	RSV OA_Lot 2

Arm description:

Participants received 1 dose of a combination of the RSVPreF3 antigen Lot 2 and AS01E adjuvant Lot B at Day 1 and were followed up until the study end (Month 6).

Arm type	Experimental
Investigational medicinal product name	RSVPreF3 OA investigational vaccine - Lot 2 + AS01E adjuvant - Lot B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose of RSVPreF3 Lot 2 vaccine reconstituted with 0.5 mL AS01E Lot B adjuvant administered intramuscularly in the deltoid region of the non-dominant arm.

Arm title	RSV OA_Lot 3

Arm description:

Participants received 1 dose of a combination of the RSVPreF3 antigen Lot 3 and AS01E adjuvant Lot C at Day 1 and were followed up until the study end (Month 6).

Arm type	Experimental

Investigational medicinal product name	RSVPreF3 OA investigational vaccine - Lot 3 + AS01E adjuvant - Lot C
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose of RSVPreF3 Lot 3 vaccine reconstituted with 0.5 mL AS01E Lot C adjuvant administered intramuscularly in the deltoid region of the non-dominant arm.

Number of subjects in period 1[1]	RSV OA_Lot 1	RSV OA_Lot 2	RSV OA_Lot 3
Started	251	253	253
Completed	249	248	248
Not completed	2	5	5
Adverse event, serious fatal	-	2	2
Lost to follow-up	2	3	3

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Out of 770 participants enrolled 757 received the study vaccine and were included in the Exposed Set.

Baseline characteristics

Reporting groups	
Reporting group title	RSV OA_Lot 1
Reporting group description:	
Participants received 1 dose of a combination of the RSVPreF3 antigen Lot 1 and AS01E adjuvant Lot A at Day 1 and were followed up until the study end (Month 6).	
Reporting group title	RSV OA_Lot 2
Reporting group description:	
Participants received 1 dose of a combination of the RSVPreF3 antigen Lot 2 and AS01E adjuvant Lot B at Day 1 and were followed up until the study end (Month 6).	
Reporting group title	RSV OA_Lot 3
Reporting group description:	
Participants received 1 dose of a combination of the RSVPreF3 antigen Lot 3 and AS01E adjuvant Lot C at Day 1 and were followed up until the study end (Month 6).	

Reporting group values	RSV OA_Lot 1	RSV OA_Lot 2	RSV OA_Lot 3
Number of subjects	251	253	253
Age categorical Units: Subjects			
<65 years	60	59	58
>=65 years	191	194	195
Age Continuous Units: Years			
arithmetic mean	69.7	70.1	69.9
standard deviation	± 6.6	± 6.6	± 6.6
Sex: Female, Male Units: Subjects			
FEMALE	131	131	109
MALE	120	122	144
Race/Ethnicity, Customized Units: Subjects			
ASIAN	6	10	10
BLACK OR AFRICAN AMERICAN	6	3	4
NATIVE HAWAIIAN/OTHER PACIFIC ISLANDER	0	1	0
OTHER: Not specified	8	8	6
WHITE	231	231	233

Reporting group values	Total		
Number of subjects	757		
Age categorical Units: Subjects			
<65 years	177		
>=65 years	580		
Age Continuous Units: Years			
arithmetic mean			
standard deviation	-		

Sex: Female, Male Units: Subjects			
FEMALE	371		
MALE	386		
Race/Ethnicity, Customized Units: Subjects			
ASIAN	26		
BLACK OR AFRICAN AMERICAN	13		
NATIVE HAWAIIAN/OTHER PACIFIC ISLANDER	1		
OTHER: Not specified	22		
WHITE	695		

End points

End points reporting groups

Reporting group title	RSV OA_Lot 1
Reporting group description:	
Participants received 1 dose of a combination of the RSVPreF3 antigen Lot 1 and AS01E adjuvant Lot A at Day 1 and were followed up until the study end (Month 6).	
Reporting group title	RSV OA_Lot 2
Reporting group description:	
Participants received 1 dose of a combination of the RSVPreF3 antigen Lot 2 and AS01E adjuvant Lot B at Day 1 and were followed up until the study end (Month 6).	
Reporting group title	RSV OA_Lot 3
Reporting group description:	
Participants received 1 dose of a combination of the RSVPreF3 antigen Lot 3 and AS01E adjuvant Lot C at Day 1 and were followed up until the study end (Month 6).	

Primary: RSVPreF3 specific immunoglobin (Ig)G antibody concentrations expressed as group geometric mean concentration (GMC)

End point title	RSVPreF3 specific immunoglobin (Ig)G antibody concentrations expressed as group geometric mean concentration (GMC)
End point description:	
Enzyme-linked immunosorbent assay (ELISA) was used to assess the concentrations of IgG antibodies against RSV PreF3 in serum samples. The analysis was performed on the Per Protocol set (PPS) which consisted of all eligible subjects who received the study intervention as per protocol, had immunogenicity results pre- and post dose, complied with blood draw intervals, without intercurrent conditions that may interfere with immunogenicity and without prohibited concomitant medication/vaccination.	
End point type	Primary
End point timeframe:	
At 30 days post-vaccination (Day 31)	

End point values	RSV OA_Lot 1	RSV OA_Lot 2	RSV OA_Lot 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	234	237	237	
Units: ELISA Units/milliliter				
geometric mean (confidence interval 95%)	86039.9 (78541.5 to 94254.3)	80518 (73150 to 88628.2)	94260.9 (86042.2 to 103264.7)	

Statistical analyses

Statistical analysis title	RSVPreF3 OA lot-to-lot consistency

Statistical analysis description:

To demonstrate the clinical equivalence of RSV OA_Lot 1 versus RSV OA_Lot 2 in terms of RSV PreF3 IgG concentrations expressed as group GMC ratio at one month post vaccination. The 2-sided 95% CI for group GMC ratio was derived from an ANCOVA model on log10 transformed RSV PreF3 IgG antibody titers. The ANCOVA model included the treatment group and the age category (age at vaccination: 60-

69, 70-79 or >=80 years) and the center as fixed effects and the pre-dose log10 titer as covariate.

Comparison groups	RSV OA_Lot 1 v RSV OA_Lot 2
Number of subjects included in analysis	471
Analysis specification	Pre-specified
Analysis type	equivalence[1]
Parameter estimate	Adjusted group GMC ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.94
upper limit	1.21

Notes:

[1] - Clinical equivalence is demonstrated if the 2 sided 95% confidence interval (CI) of the GMC ratios (RSV OA_Lot 1 divided by RSV OA_Lot 2) is within the pre defined limit of [0.67, 1.5].

Statistical analysis title	RSVPreF3 OA lot-to-lot consistency

Statistical analysis description:

To demonstrate the clinical equivalence of RSV OA_Lot 1 versus RSV OA_Lot 3 in terms of RSV PreF3 IgG concentrations expressed as group GMC ratio at one month post vaccination. The 2-sided 95% CI for group GMC ratio was derived from an ANCOVA model on log10 transformed RSV PreF3 IgG antibody titers. The ANCOVA model included the treatment group and the age category (age at vaccination: 60-69, 70-79 or >=80 years) and the center as fixed effects and the pre-dose log10 titer as covariate.

Comparison groups	RSV OA_Lot 1 v RSV OA_Lot 3
Number of subjects included in analysis	471
Analysis specification	Pre-specified
Analysis type	equivalence[2]
Parameter estimate	Adjusted group GMC ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.04

Notes:

[2] - Clinical equivalence is demonstrated if the 2 sided 95% confidence interval (CI) of the GMC ratios (RSV OA_Lot 1 divided by RSV OA_Lot 3) is within the pre defined limit of [0.67, 1.5].

Statistical analysis title	RSVPreF3 OA lot-to-lot consistency

Statistical analysis description:

To demonstrate the clinical equivalence of RSV OA_Lot 2 versus RSV OA_Lot 3 in terms of RSV PreF3 IgG concentrations expressed as group GMC ratio at one month post vaccination. The 2-sided 95% CI for group GMC ratio was derived from an ANCOVA model on log10 transformed RSV PreF3 IgG antibody titers. The ANCOVA model included the treatment group and the age category (age at vaccination: 60-69, 70-79 or >=80 years) and the center as fixed effects and the pre-dose log10 titer as covariate.

Comparison groups	RSV OA_Lot 2 v RSV OA_Lot 3
Number of subjects included in analysis	474
Analysis specification	Pre-specified
Analysis type	equivalence[3]
Parameter estimate	Adjusted group GMC ratio
Point estimate	0.87

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	0.99

Notes:

[3] - Clinical equivalence is demonstrated if the 2 sided 95% confidence interval (CI) of the GMC ratios (RSV OA_Lot 2 divided by RSV OA_Lot 3) is within the pre defined limit of [0.67, 1.5].

Secondary: RSVPreF3 specific IgG antibody concentrations expressed as mean geometric increase (MGI)

End point title	RSVPreF3 specific IgG antibody concentrations expressed as mean geometric increase (MGI)

End point description:

MGI was defined as the geometric mean of the within participant ratios of the post-vaccination RSV PreF3 IgG concentration over the pre-vaccination RSV PreF3 IgG concentration. The analysis was performed on the PPS which consisted of all eligible subjects who received the study intervention as per protocol, had immunogenicity results pre- and post dose, complied with blood draw intervals, without intercurrent conditions that may interfere with immunogenicity and without prohibited concomitant medication/vaccination.

End point type	Secondary

End point timeframe:

At 30 days post-vaccination (Day 31)

End point values	RSV OA_Lot 1	RSV OA_Lot 2	RSV OA_Lot 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	234	237	237	
Units: Ratio				
geometric mean (confidence interval 95%)	11.84 (10.53 to 13.31)	11.29 (10.12 to 12.6)	12.46 (11.13 to 13.94)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants reporting solicited administration site events

End point title	Percentage of participants reporting solicited administration site events

End point description:

Solicited administration site adverse events (AEs) assessed were erythema, pain and swelling. Any = occurrence of the adverse event regardless of intensity grade. The analysis was performed on participants of the Exposed Set (ES) who had their diary cards completed. The ES included all subjects who received the study intervention.

End point type	Secondary

End point timeframe:

Within 4 days (the day of vaccination and 3 subsequent days) after study intervention administration

End point values	RSV OA_Lot 1	RSV OA_Lot 2	RSV OA_Lot 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	249	251	252	
Units: Percentage of participants				
number (confidence interval 95%)				
Erythema	12.4 (8.6 to 17.2)	11.6 (7.9 to 16.2)	13.5 (9.5 to 18.3)	
Pain	58.2 (51.8 to 64.4)	65.7 (59.5 to 71.6)	62.7 (56.4 to 68.7)	
Swelling	6.8 (4 to 10.7)	7.6 (4.6 to 11.6)	7.9 (4.9 to 12)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants reporting solicited systemic events

End point title	Percentage of participants reporting solicited systemic events

End point description:

Solicited systemic events assessed were arthralgia, fatigue, fever [defined as temperature equal to or above (>=) 38 degrees Celsius (°C)/100.4 degrees Fahrenheit (°F)], headache and myalgia. Any = occurrence of the adverse event regardless of intensity grade or relation to study vaccination. The analysis was performed on participants of the Exposed Set (ES) who had their diary cards completed. The ES included all subjects who received the study intervention.

End point type	Secondary

End point timeframe:

Within 4 days (the day of vaccination and 3 subsequent days) after study intervention administration

End point values	RSV OA_Lot 1	RSV OA_Lot 2	RSV OA_Lot 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	249	251	252	
Units: Percentage of participants				
number (confidence interval 95%)				
Arthralgia	13.3 (9.3 to 18.1)	13.9 (9.9 to 18.9)	14.7 (10.6 to 19.7)	
Fatigue	28.1 (22.6 to 34.1)	25.9 (20.6 to 31.8)	27.8 (22.3 to 33.7)	
Fever	2 (0.7 to 4.6)	1.6 (0.4 to 4)	2.8 (1.1 to 5.6)	
Headache	25.7 (20.4 to 31.6)	23.5 (18.4 to 29.2)	22.2 (17.2 to 27.9)	
Myalgia	31.3 (25.6 to 37.5)	34.3 (28.4 to 40.5)	33.7 (27.9 to 39.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants reporting at least one unsolicited adverse event

End point title	Percentage of participants reporting at least one unsolicited adverse event

End point description:

An unsolicited AE is 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 was reported as an unsolicited AE. Unsolicited AEs include serious, non-serious AEs and potential immune-mediated diseases (pIMDs). The analysis was performed on the ES, which included all subjects who received the study intervention.

End point type	Secondary

End point timeframe:

Within 30 days (the day of vaccination and 29 subsequent days) after study intervention administration

End point values	RSV OA_Lot 1	RSV OA_Lot 2	RSV OA_Lot 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	251	253	253	
Units: Percentage of participants				
number (confidence interval 95%)	14.7 (10.6 to 19.7)	14.6 (10.5 to 19.6)	13.4 (9.5 to 18.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants reporting at least one serious adverse event (SAE)

End point title	Percentage of participants reporting at least one serious adverse event (SAE)

End point description:

An SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect in the offspring of a study participant. Any = occurrence of the symptom regardless of intensity grade or relationship to vaccination. The analysis was performed on the ES, which included all subjects who received the study intervention.

End point type	Secondary

End point timeframe:

From Day 1 up to study end (6 months after vaccination)

End point values	RSV OA_Lot 1	RSV OA_Lot 2	RSV OA_Lot 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	251	253	253	
Units: Percentage of Participants				
number (confidence interval 95%)	3.2 (1.4 to 6.2)	2.4 (0.9 to 5.1)	2.8 (1.1 to 5.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants reporting at least onepotential immune-mediated disease (pIMD)

End point title	Percentage of participants reporting at least onepotential immune-mediated disease (pIMD)

End point description:

pIMDs are a subset of AEs of special interest that include autoimmune diseases and other inflammatory and/or neurologic disorders of interest which may or may not have an autoimmune etiology. The analysis was performed on the ES, which included all subjects who received the study intervention.

End point type	Secondary

End point timeframe:

From Day 1 up to study end (6 months after vaccination)

End point values	RSV OA_Lot 1	RSV OA_Lot 2	RSV OA_Lot 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	251	253	253	
Units: Percentage of participants				
number (confidence interval 95%)	0.8 (0.1 to 2.8)	0.4 (0 to 2.2)	1.2 (0.2 to 3.4)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs were collected during the 4-day follow-up period after vaccination. Unsolicited AEs were collected during the 30-day follow-up period after vaccination. SAEs and pIMDs were collected from Day 1 to Study end (6 months after vaccination).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	RSV OA_Lot 1

Reporting group description:

Participants received 1 dose of a combination of the RSVPreF3 antigen Lot 1 and AS01E adjuvant Lot A at Day 1 and were followed up until the study end (Month 6).

Reporting group title	RSV OA_Lot 2

Reporting group description:

Participants received 1 dose of a combination of the RSVPreF3 antigen Lot 2 and AS01E adjuvant Lot B at Day 1 and were followed up until the study end (Month 6).

Reporting group title	RSV OA_Lot 3

Reporting group description:

Participants received 1 dose of a combination of the RSVPreF3 antigen Lot 3 and AS01E adjuvant Lot C at Day 1 and were followed up until the study end (Month 6).

Serious adverse events	RSV OA_Lot 1	RSV OA_Lot 2	RSV OA_Lot 3
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 251 (3.19%)	6 / 253 (2.37%)	7 / 253 (2.77%)
number of deaths (all causes)	0	2	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to liver			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lymph nodes			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			

subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the hypopharynx			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (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
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	1 / 253 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Myocardial infarction			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Sudden cardiac death			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	2 / 253 (0.79%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary oedema			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			

subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urethral stenosis			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (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
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (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
Pneumonia			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (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
Sepsis			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Gout			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (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
Malnutrition			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (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: 0 %

Non-serious adverse events	RSV OA_Lot 1	RSV OA_Lot 2	RSV OA_Lot 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	181 / 251 (72.11%)	192 / 253 (75.89%)	195 / 253 (77.08%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	145 / 251 (57.77%)	165 / 253 (65.22%)	159 / 253 (62.85%)
occurrences (all)	145	165	160
Fatigue			
subjects affected / exposed	70 / 251 (27.89%)	66 / 253 (26.09%)	72 / 253 (28.46%)
occurrences (all)	70	66	72
Injection site erythema			
subjects affected / exposed	32 / 251 (12.75%)	29 / 253 (11.46%)	37 / 253 (14.62%)
occurrences (all)	32	29	37
Injection site swelling			
subjects affected / exposed	17 / 251 (6.77%)	20 / 253 (7.91%)	20 / 253 (7.91%)
occurrences (all)	17	20	20
Pyrexia			
subjects affected / exposed	8 / 251 (3.19%)	9 / 253 (3.56%)	9 / 253 (3.56%)
occurrences (all)	8	9	9
Chest discomfort			
subjects affected / exposed	1 / 251 (0.40%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	1	1	0

Chills			
subjects affected / exposed	0 / 251 (0.00%)	2 / 253 (0.79%)	0 / 253 (0.00%)
occurrences (all)	0	2	0
Malaise			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	1 / 253 (0.40%)
occurrences (all)	0	1	1
Chest pain			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Tenderness			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Vaccination site pain			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	3 / 251 (1.20%)	3 / 253 (1.19%)	1 / 253 (0.40%)
occurrences (all)	3	3	1
Asthma			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	1	0	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	2 / 253 (0.79%)
occurrences (all)	0	0	2
Cough			

subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	2 / 253 (0.79%)
occurrences (all)	0	0	2
Rhinorrhoea			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	1	0	1
Catarrh			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Nasal discomfort			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Nasal obstruction			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Pulmonary mass			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 251 (0.40%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	1	1	0
Investigations			
Computerised tomogram head abnormal			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Procedural pain			
subjects affected / exposed	0 / 251 (0.00%)	2 / 253 (0.79%)	0 / 253 (0.00%)
occurrences (all)	0	2	0
Fall			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Fibula fracture			

subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Foreign body in respiratory tract			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Injury			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Muscle strain			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Skin laceration			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Palpitations			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	65 / 251 (25.90%)	62 / 253 (24.51%)	57 / 253 (22.53%)
occurrences (all)	68	64	59
Dizziness			
subjects affected / exposed	1 / 251 (0.40%)	1 / 253 (0.40%)	1 / 253 (0.40%)
occurrences (all)	1	1	1
Migraine			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	2 / 253 (0.79%)
occurrences (all)	0	1	2
Ophthalmic migraine			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Sciatica			

subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Vertigo positional			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Eye disorders			
Age-related macular degeneration			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Ocular hyperaemia			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 251 (0.80%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	2	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	1 / 253 (0.40%)
occurrences (all)	0	1	1
Nausea			
subjects affected / exposed	1 / 251 (0.40%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	1	1	0
Abdominal discomfort			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Abdominal distension			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Dyspepsia			

subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Glossodynia			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Oral mucosal blistering			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Oral pain			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	2 / 251 (0.80%)	2 / 253 (0.79%)	3 / 253 (1.19%)
occurrences (all)	2	2	3
Erythema			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	1 / 253 (0.40%)
occurrences (all)	0	1	1
Psoriasis			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	2 / 253 (0.79%)
occurrences (all)	0	0	2
Dermatitis contact			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0

Rosacea			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Chronic kidney disease			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	78 / 251 (31.08%)	87 / 253 (34.39%)	86 / 253 (33.99%)
occurrences (all)	78	87	86
Arthralgia			
subjects affected / exposed	34 / 251 (13.55%)	36 / 253 (14.23%)	39 / 253 (15.42%)
occurrences (all)	34	37	39
Back pain			
subjects affected / exposed	1 / 251 (0.40%)	1 / 253 (0.40%)	1 / 253 (0.40%)
occurrences (all)	1	1	1
Bursitis			
subjects affected / exposed	1 / 251 (0.40%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	1	1	0
Pain in extremity			
subjects affected / exposed	0 / 251 (0.00%)	2 / 253 (0.79%)	0 / 253 (0.00%)
occurrences (all)	0	2	0
Arthritis			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Musculoskeletal stiffness			

subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Osteoarthritis			
subjects affected / exposed	1 / 251 (0.40%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	1	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	3 / 251 (1.20%)	2 / 253 (0.79%)	1 / 253 (0.40%)
occurrences (all)	3	2	1
Urinary tract infection			
subjects affected / exposed	3 / 251 (1.20%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	3	0	0
COVID-19			
subjects affected / exposed	2 / 251 (0.80%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	2	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 251 (0.80%)	0 / 253 (0.00%)	0 / 253 (0.00%)
occurrences (all)	2	0	0
Bronchitis			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis caliciviral			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1

Herpes zoster			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Postoperative wound infection			
subjects affected / exposed	0 / 251 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed	0 / 251 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences (all)	0	1	0

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