



Clinical trial results:

A Phase 2, Randomized, Observer-blind Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1345, an mRNA Vaccine Targeting Respiratory Syncytial Virus, in Children 2 to <18 Years of Age at High Risk of Respiratory Syncytial Virus Disease

Summary

EudraCT number	2024-000502-15
Trial protocol	Outside EU/EEA
Global end of trial date	27 August 2025

Results information

Result version number	v1 (current)
This version publication date	14 March 2026
First version publication date	14 March 2026

Trial information

Trial identification

Sponsor protocol code	mRNA-1345-P202
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT06097299
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	ModernaTX, Inc.
Sponsor organisation address	325 Binney Street, Cambridge, United States, 02142
Public contact	Moderna WeCare Team, ModernaTX, Inc., +1 866-663-3762, WeCareClinicalTrials@modernatx.com
Scientific contact	Moderna WeCare Team, ModernaTX, Inc., +1 866-663-3762, WeCareClinicalTrials@modernatx.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 August 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 August 2025
Global end of trial reached?	Yes
Global end of trial date	27 August 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of Cohort 1 and Cohort 2 Part A was to evaluate the safety and reactogenicity of a single study injection. The primary objective of Cohort 1 Part B was to evaluate the incidence of respiratory syncytial virus (RSV)-associated respiratory tract disease (RSV-RTD) during 6 months after re-enrollment.

Protection of trial subjects:

This study was conducted in accordance with the protocol and consensus ethical principles derived from international guidelines including the Declaration of Helsinki, Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines, applicable International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, and other applicable laws and regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 October 2023
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 349
Worldwide total number of subjects	349
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)	255
Adolescents (12-17 years)	94
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study consisted of 2 parts (Parts A and B). Part A consisted of 2 cohorts. For Part B, all Cohort 1 participants who were enrolled and dosed in Part A, were offered to re-enroll into the safety follow-up study. Participants who were in Part B were not administered any study drug.

Period 1

Period 1 title	Part A
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Blinding implementation details:

The study was observer-blind.

Arms

Are arms mutually exclusive?	Yes
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Arm title	Part A Cohort 1: Placebo
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Arm description:

Participants received a single intramuscular (IM) injection of placebo on Day 1.

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

Dosage and administration details:

Placebo matched to mRNA-1345 was administered per schedule specified in the arm description.

Arm title	Part A Cohort 1: mRNA-1345 Dose Level 1
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Arm description:

Participants received a single IM injection of mRNA-1345 at Dose Level 1 on Day 1.

Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per schedule specified in the arm description.

Arm title	Part A Cohort 1: mRNA-1345 Dose Level 2
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Arm description:

Participants received a single IM injection of mRNA-1345 at Dose Level 2 on Day 1.

Arm type	Experimental
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Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
mRNA-1345 was administered per schedule specified in the arm description.	
Arm title	Part A Cohort 1: mRNA-1345 Dose Level 3
Arm description:	
Participants received a single IM injection of mRNA-1345 at Dose Level 3 on Day 1.	
Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
mRNA-1345 was administered per schedule specified in the arm description.	
Arm title	Part A Cohort 2: mRNA-1345 Dose Level 2
Arm description:	
Participants received a single IM injection of mRNA-1345 at Dose Level 2 on Day 1.	
Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
mRNA-1345 was administered per schedule specified in the arm description.	
Arm title	Part A Cohort 2: mRNA-1345 Dose Level 3
Arm description:	
Participants received a single IM injection of mRNA-1345 at Dose Level 3 on Day 1.	
Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
mRNA-1345 was administered per schedule specified in the arm description.	
Arm title	Part A Cohort 2: mRNA-1345 Dose Level 4
Arm description:	
Participants received a single IM injection of mRNA-1345 at Dose Level 4 on Day 1.	
Arm type	Experimental
Investigational medicinal product name	mRNA-1345
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1345 was administered per schedule specified in the arm description.

Number of subjects in period 1	Part A Cohort 1: Placebo	Part A Cohort 1: mRNA-1345 Dose Level 1	Part A Cohort 1: mRNA-1345 Dose Level 2
Started	41	40	42
Received Study Drug Injection	41	39	41
Completed	35	36	37
Not completed	6	4	5
Other Than Specified	-	-	1
Withdrawal by Parent/Guardian	2	-	-
Lost to follow-up	4	3	4
Protocol deviation	-	1	-

Number of subjects in period 1	Part A Cohort 1: mRNA-1345 Dose Level 3	Part A Cohort 2: mRNA-1345 Dose Level 2	Part A Cohort 2: mRNA-1345 Dose Level 3
Started	41	62	61
Received Study Drug Injection	41	61	61
Completed	40	60	59
Not completed	1	2	2
Other Than Specified	-	-	-
Withdrawal by Parent/Guardian	-	2	-
Lost to follow-up	1	-	2
Protocol deviation	-	-	-

Number of subjects in period 1	Part A Cohort 2: mRNA-1345 Dose Level 4
Started	62
Received Study Drug Injection	62
Completed	59
Not completed	3
Other Than Specified	-
Withdrawal by Parent/Guardian	-
Lost to follow-up	3
Protocol deviation	-

Period 2	
Period 2 title	Part B
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor
Blinding implementation details: The study was observer-blind.	
Arms	
Are arms mutually exclusive?	Yes
Arm title	Part B Cohort 1: Received Placebo in Part A
Arm description: Participants who received placebo in Part A and decided to continue in Part B of the study were followed up for safety assessment (for up to 6 months). Participants did not receive any study drug in Part B.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Part B Cohort 1: Received mRNA-1345 Dose Level 1 in Part A
Arm description: Participants who received mRNA-1345 at Dose Level 1 in Part A and decided to continue in Part B of the study were followed up for safety assessment (for up to 6 months). Participants did not receive any study drug in Part B.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Part B Cohort 1: Received mRNA-1345 Dose Level 2 in Part A
Arm description: Participants who received mRNA-1345 at Dose Level 2 in Part A and decided to continue in Part B of the study were followed up for safety assessment (for up to 6 months). Participants did not receive any study drug in Part B.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Part B Cohort 1: Received mRNA-1345 Dose Level 3 in Part A
Arm description: Participants who received mRNA-1345 at Dose Level 3 in Part A and decided to continue in Part B of the study were followed up for safety assessment (for up to 6 months). Participants did not receive any study drug in Part B.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 2 ^[1]	Part B Cohort 1: Received Placebo in Part A	Part B Cohort 1: Received mRNA-1345 Dose Level 1 in Part A	Part B Cohort 1: Received mRNA-1345 Dose Level 2 in Part A
Started	19	24	25
Completed	19	24	25
Not completed	0	0	0

Lost to follow-up	-	-	-
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Number of subjects in period 2^[1]	Part B Cohort 1: Received mRNA-1345 Dose Level 3 in Part A
Started	24
Completed	23
Not completed	1
Lost to follow-up	1

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all participants who completed Part A were re-enrolled in Part B.

Baseline characteristics

Reporting groups

Reporting group title	Part A Cohort 1: Placebo
Reporting group description:	
Participants received a single intramuscular (IM) injection of placebo on Day 1.	
Reporting group title	Part A Cohort 1: mRNA-1345 Dose Level 1
Reporting group description:	
Participants received a single IM injection of mRNA-1345 at Dose Level 1 on Day 1.	
Reporting group title	Part A Cohort 1: mRNA-1345 Dose Level 2
Reporting group description:	
Participants received a single IM injection of mRNA-1345 at Dose Level 2 on Day 1.	
Reporting group title	Part A Cohort 1: mRNA-1345 Dose Level 3
Reporting group description:	
Participants received a single IM injection of mRNA-1345 at Dose Level 3 on Day 1.	
Reporting group title	Part A Cohort 2: mRNA-1345 Dose Level 2
Reporting group description:	
Participants received a single IM injection of mRNA-1345 at Dose Level 2 on Day 1.	
Reporting group title	Part A Cohort 2: mRNA-1345 Dose Level 3
Reporting group description:	
Participants received a single IM injection of mRNA-1345 at Dose Level 3 on Day 1.	
Reporting group title	Part A Cohort 2: mRNA-1345 Dose Level 4
Reporting group description:	
Participants received a single IM injection of mRNA-1345 at Dose Level 4 on Day 1.	

Reporting group values	Part A Cohort 1: Placebo	Part A Cohort 1: mRNA-1345 Dose Level 1	Part A Cohort 1: mRNA-1345 Dose Level 2
Number of subjects	41	40	42
Age Categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	41	40	42
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender Categorical			
Units: Subjects			
Female	20	22	17
Male	21	18	25
Race			
Units: Subjects			
White	25	26	32
Black or African American	14	11	6

Asian	1	1	1
Multiple	1	2	3
Ethnicity			
Units: Subjects			
Hispanic or Latino	14	11	14
Not Hispanic or Latino	27	29	28

Reporting group values	Part A Cohort 1: mRNA-1345 Dose Level 3	Part A Cohort 2: mRNA-1345 Dose Level 2	Part A Cohort 2: mRNA-1345 Dose Level 3
Number of subjects	41	62	61
Age Categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	41	30	30
Adolescents (12-17 years)	0	32	31
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender Categorical			
Units: Subjects			
Female	26	33	23
Male	15	29	38
Race			
Units: Subjects			
White	30	38	27
Black or African American	8	20	31
Asian	2	1	0
Multiple	1	3	3
Ethnicity			
Units: Subjects			
Hispanic or Latino	19	14	17
Not Hispanic or Latino	22	48	44

Reporting group values	Part A Cohort 2: mRNA-1345 Dose Level 4	Total	
Number of subjects	62	349	
Age Categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	31	255	
Adolescents (12-17 years)	31	94	
Adults (18-64 years)	0	0	

From 65-84 years	0	0	
85 years and over	0	0	

Gender Categorical			
Units: Subjects			
Female	35	176	
Male	27	173	

Race			
Units: Subjects			
White	31	209	
Black or African American	28	118	
Asian	1	7	
Multiple	2	15	

Ethnicity			
Units: Subjects			
Hispanic or Latino	15	104	
Not Hispanic or Latino	47	245	

End points

End points reporting groups

Reporting group title	Part A Cohort 1: Placebo
Reporting group description: Participants received a single intramuscular (IM) injection of placebo on Day 1.	
Reporting group title	Part A Cohort 1: mRNA-1345 Dose Level 1
Reporting group description: Participants received a single IM injection of mRNA-1345 at Dose Level 1 on Day 1.	
Reporting group title	Part A Cohort 1: mRNA-1345 Dose Level 2
Reporting group description: Participants received a single IM injection of mRNA-1345 at Dose Level 2 on Day 1.	
Reporting group title	Part A Cohort 1: mRNA-1345 Dose Level 3
Reporting group description: Participants received a single IM injection of mRNA-1345 at Dose Level 3 on Day 1.	
Reporting group title	Part A Cohort 2: mRNA-1345 Dose Level 2
Reporting group description: Participants received a single IM injection of mRNA-1345 at Dose Level 2 on Day 1.	
Reporting group title	Part A Cohort 2: mRNA-1345 Dose Level 3
Reporting group description: Participants received a single IM injection of mRNA-1345 at Dose Level 3 on Day 1.	
Reporting group title	Part A Cohort 2: mRNA-1345 Dose Level 4
Reporting group description: Participants received a single IM injection of mRNA-1345 at Dose Level 4 on Day 1.	
Reporting group title	Part B Cohort 1: Received Placebo in Part A
Reporting group description: Participants who received placebo in Part A and decided to continue in Part B of the study were followed up for safety assessment (for up to 6 months). Participants did not receive any study drug in Part B.	
Reporting group title	Part B Cohort 1: Received mRNA-1345 Dose Level 1 in Part A
Reporting group description: Participants who received mRNA-1345 at Dose Level 1 in Part A and decided to continue in Part B of the study were followed up for safety assessment (for up to 6 months). Participants did not receive any study drug in Part B.	
Reporting group title	Part B Cohort 1: Received mRNA-1345 Dose Level 2 in Part A
Reporting group description: Participants who received mRNA-1345 at Dose Level 2 in Part A and decided to continue in Part B of the study were followed up for safety assessment (for up to 6 months). Participants did not receive any study drug in Part B.	
Reporting group title	Part B Cohort 1: Received mRNA-1345 Dose Level 3 in Part A
Reporting group description: Participants who received mRNA-1345 at Dose Level 3 in Part A and decided to continue in Part B of the study were followed up for safety assessment (for up to 6 months). Participants did not receive any study drug in Part B.	

Primary: Part A (Cohorts 1 and 2): Number of Participants with Solicited Local and Systemic Adverse Reactions (ARs)

End point title	Part A (Cohorts 1 and 2): Number of Participants with Solicited Local and Systemic Adverse Reactions (ARs) ^[1]
End point description: Solicited ARs were collected in an electronic diary (eDiary). Local ARs: injection site pain, erythema (redness), swelling/induration (hardness); and axillary (underarm) swelling or tenderness ipsilateral to	

the side of injection. Systemic ARs: fever, headache, fatigue, myalgia, arthralgia, nausea/vomiting, and chills. Note, not all solicited ARs were considered adverse events (AEs). Investigator reviewed whether the solicited AR was also to be recorded as an AE. A summary of serious AEs (SAEs) and nonserious AEs ("Other"), regardless of causality, is located in the "Reported Adverse Events" section. Solicited Safety Set included all randomized participants who received the study intervention and who contributed any solicited AR data.

End point type	Primary
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End point timeframe:

Up to 7 days postinjection

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: The endpoint is descriptive in nature.

End point values	Part A Cohort 1: Placebo	Part A Cohort 1: mRNA-1345 Dose Level 1	Part A Cohort 1: mRNA-1345 Dose Level 2	Part A Cohort 1: mRNA-1345 Dose Level 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	39	41	41
Units: participants	18	21	28	30

End point values	Part A Cohort 2: mRNA-1345 Dose Level 2	Part A Cohort 2: mRNA-1345 Dose Level 3	Part A Cohort 2: mRNA-1345 Dose Level 4	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	61	62	
Units: participants	45	44	51	

Statistical analyses

No statistical analyses for this end point

Primary: Part A (Cohorts 1 and 2): Number of Participants with Unsolicited Adverse Events (AEs)

End point title	Part A (Cohorts 1 and 2): Number of Participants with Unsolicited Adverse Events (AEs) ^[2]
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End point description:

An AE was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. Any abnormal laboratory test result (hematology, clinical chemistry, or prothrombin time [PT]/partial thromboplastin time [PTT]) or other safety assessment (for example, electrocardiogram, radiological scan, vital sign measurement), including one that worsened from baseline and was considered clinically significant in the medical and scientific judgment of the Investigator was recorded as an AE. A summary of SAEs and all nonserious AEs ("Other"), regardless of causality, is located in the "Reported Adverse Events" section. Part A Safety Set included all randomized participants who received the study intervention.

End point type	Primary
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End point timeframe:

Up to 28 days postinjection

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: The endpoint is descriptive in nature.

End point values	Part A Cohort 1: Placebo	Part A Cohort 1: mRNA-1345 Dose Level 1	Part A Cohort 1: mRNA-1345 Dose Level 2	Part A Cohort 1: mRNA-1345 Dose Level 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	39	41	41
Units: participants	9	9	3	10

End point values	Part A Cohort 2: mRNA-1345 Dose Level 2	Part A Cohort 2: mRNA-1345 Dose Level 3	Part A Cohort 2: mRNA-1345 Dose Level 4	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	61	62	
Units: participants	11	5	6	

Statistical analyses

No statistical analyses for this end point

Primary: Part A (Cohorts 1 and 2): Number of Participants With Medically Attended AEs (MAAEs), Adverse Events of Special Interest (AESIs), Serious Adverse Events (SAEs), and AEs Leading to Study Discontinuation

End point title	Part A (Cohorts 1 and 2): Number of Participants With Medically Attended AEs (MAAEs), Adverse Events of Special Interest (AESIs), Serious Adverse Events (SAEs), and AEs Leading to Study Discontinuation ^[3]
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End point description:

A MAAE was an AE that led to an unscheduled visit to a healthcare practitioner. An AESI was an AE (serious or nonserious) of scientific and medical concern specific to the Sponsor's product or program, for which ongoing monitoring and immediate notification by the Investigator to the Sponsor are required. An SAE was defined as any AE that resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in disability, was a congenital anomaly/birth defect, or was an important medical event. A summary of SAEs and all nonserious AEs ("Other"), regardless of causality, is located in the "Reported Adverse Events" section. Part A Safety Set included all randomized participants who received the study intervention.

End point type	Primary
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End point timeframe:

Day 1 through end of Part A (Month 6)

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: The endpoint is descriptive in nature.

End point values	Part A Cohort 1: Placebo	Part A Cohort 1: mRNA-1345 Dose Level 1	Part A Cohort 1: mRNA-1345 Dose Level 2	Part A Cohort 1: mRNA-1345 Dose Level 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	39	41	41
Units: participants				
MAAEs	3	4	5	9
AESIs	0	0	0	0
SAEs	0	0	0	0
AEs Leading to Study Discontinuation	0	0	0	0

End point values	Part A Cohort 2: mRNA-1345 Dose Level 2	Part A Cohort 2: mRNA-1345 Dose Level 3	Part A Cohort 2: mRNA-1345 Dose Level 4	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	61	62	
Units: participants				
MAAEs	10	8	9	
AESIs	0	0	0	
SAEs	0	0	3	
AEs Leading to Study Discontinuation	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Part B (Cohort 1): Number of participants With RSV-RTD, Respiratory syncytial virus- Lower Respiratory Tract Disease (RSV-LRTD), Severe RSV-LRTD, Very Severe RSV-LRTD and RSV Hospitalization Classified by Clinical Assessment Team (CAT)

End point title	Part B (Cohort 1): Number of participants With RSV-RTD, Respiratory syncytial virus- Lower Respiratory Tract Disease (RSV-LRTD), Severe RSV-LRTD, Very Severe RSV-LRTD and RSV Hospitalization Classified by Clinical Assessment Team (CAT) ^[4]
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End point description:

RSV-RTD: Runny nose or blocked nose or cough and confirmed RSV infection. RSV-LRTD: Cough or difficulty breathing (Based on Investigator's observation; difficulty breathing included signs of wheezing, stridor, tachypnoea, chest in-drawing or subcostal or intercostal retractions) and peripheral oxygen saturation (SpO2) <95%, or respiratory rate (RR) increased and confirmed RSV infection. RSV Severe-LRTD: Meeting the definition of RSV-LRTD and SpO2 <93%, or lower chest wall in-drawing. RSV Very Severe LRTD: Meeting the definition of RSV-LRTD and SpO2 <90%, or failure to respond/unconscious. RSV Hospitalization: Confirmed RSV and hospitalized for acute medical condition. Part B Cohort 1 Safety Set included all participants in the Part A Cohort 1 Safety Set who re-enrolled in Part B of the study.

End point type	Primary
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End point timeframe:

Day 1 through end of Part B (Month 6)

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: The endpoint is descriptive in nature.

End point values	Part B Cohort 1: Received Placebo in Part A	Part B Cohort 1: Received mRNA-1345 Dose Level 1 in Part A	Part B Cohort 1: Received mRNA-1345 Dose Level 2 in Part A	Part B Cohort 1: Received mRNA-1345 Dose Level 3 in Part A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	24	25	24
Units: participants				
RSV-RTD	0	2	1	2
RSV-LRTD	0	1	0	0

RSV Severe LRTD	0	0	0	0
RSV Very-Severe LRTD	0	0	0	0
RSV Hospitalization	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Cohort 1): Geometric Mean Titer (GMT) of Serum RSV Neutralizing Antibody

End point title	Part A (Cohort 1): Geometric Mean Titer (GMT) of Serum RSV Neutralizing Antibody ^[5]
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End point description:

Antibody values reported as below lower limit of quantification (LLOQ) were replaced by 0.5*LLOQ. Values greater than the upper limit of quantification (ULOQ) were replaced by the ULOQ. LLOQ was 13 international units (IU)/milliliter (mL) for RSV-A and 10 IU/mL for RSV-B. ULOQ was 259061 IU/mL for RSV-A and 112476 IU/mL for RSV-B. 95% confidence interval (CI) for geometric mean (GM) value was calculated based on the t-distribution of the log-transformed values, then back transformed to the original scale for presentation. Per-Protocol (PP) Set included all randomized participants who received the study injection, complied with the immunogenicity testing schedule, had a Baseline and Day 29 assessment, and had no important protocol deviations that affected the immune response. 'n' = participants evaluable for specified categories.

End point type	Secondary
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End point timeframe:

Day 1, Day 29, and Month 6

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The endpoint is reporting statistics for the specified arms only.

End point values	Part A Cohort 1: Placebo	Part A Cohort 1: mRNA-1345 Dose Level 1	Part A Cohort 1: mRNA-1345 Dose Level 2	Part A Cohort 1: mRNA-1345 Dose Level 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	38	41	39
Units: IU/mL				
geometric mean (confidence interval 95%)				
RSV-A: Day 1 (n=39,38,41,39)	742.79 (406.66 to 1356.75)	636.62 (335.51 to 1207.99)	925.12 (553.23 to 1546.99)	1100.06 (642.50 to 1883.48)
RSV-A: Day 29 (n=39,38,41,39)	622.62 (365.59 to 1060.36)	7548.68 (4715.49 to 12084.11)	5454.33 (3321.91 to 8955.59)	13963.62 (8733.17 to 22326.68)
RSV-A: Month 6 (n=33,34,35,38)	767.32 (521.91 to 1128.13)	1978.73 (1207.90 to 3241.47)	1975.68 (1339.27 to 2914.51)	4129.82 (2471.64 to 6900.43)
RSV-B: Day 1 (n=39,38,41,39)	343.19 (193.35 to 609.18)	333.68 (187.03 to 595.33)	478.93 (293.74 to 780.85)	442.16 (266.78 to 732.83)
RSV-B: Day 29 (n=37,38,41,39)	310.51 (190.05 to 507.33)	2439.14 (1542.12 to 3857.94)	2043.38 (1282.91 to 3254.64)	3913.01 (2665.38 to 5744.65)
RSV-B: Month 6 (n=33,34,35,38)	351.86 (259.00 to 478.01)	708.25 (448.51 to 1118.41)	746.17 (533.81 to 1043.00)	975.64 (654.64 to 1454.04)

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Cohort 1): Geometric Mean Concentration (GMC) of Serum RSV Prefusion F (Pre-F) Binding Antibody

End point title	Part A (Cohort 1): Geometric Mean Concentration (GMC) of Serum RSV Prefusion F (Pre-F) Binding Antibody ^[6]
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End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ. Values greater than ULOQ were replaced by the ULOQ. LLOQ was 35 arbitrary units (AU)/mL and ULOQ was 580553 AU/mL for RSV Pre-F immunoglobulin G (IgG) antibody. 95% CI for GM value was calculated based on the t-distribution of the log-transformed values, then back transformed to the original scale for presentation. PP Set included all randomized participants who received the study injection, complied with the immunogenicity testing schedule, had a Baseline and Day 29 assessment, and had no important protocol deviations that affected the immune response. 'n' = participants evaluable for specified categories.

End point type	Secondary
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End point timeframe:

Day 1, Day 29, and Month 6

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The endpoint is reporting statistics for the specified arms only.

End point values	Part A Cohort 1: Placebo	Part A Cohort 1: mRNA-1345 Dose Level 1	Part A Cohort 1: mRNA-1345 Dose Level 2	Part A Cohort 1: mRNA-1345 Dose Level 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	38	41	39
Units: AU/mL				
geometric mean (confidence interval 95%)				
Day 1 (n=38,38,41,39)	5666.73 (2740.28 to 11718.45)	4824.82 (2238.62 to 10398.78)	7759.79 (4418.08 to 13629.08)	9200.11 (5456.47 to 15512.24)
Day 29 (n=39,36,39,39)	5478.04 (2980.57 to 10068.20)	60354.43 (43293.29 to 84139.08)	52861.15 (36058.06 to 77494.50)	93443.87 (69910.72 to 124898.70)
Month 6 (n=33,32,35,38)	6021.94 (4130.25 to 8780.02)	13070.48 (8101.85 to 21086.21)	14422.57 (10902.68 to 19078.86)	20054.12 (13907.99 to 28916.31)

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Cohort 1): Geometric Mean Fold Rise (GMFR) of Postbaseline/Baseline Neutralizing Antibody Titers

End point title	Part A (Cohort 1): Geometric Mean Fold Rise (GMFR) of Postbaseline/Baseline Neutralizing Antibody Titers ^[7]
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End point description:

Antibody values reported as below lower LLOQ were replaced by 0.5*LLOQ. Values greater than the ULOQ were replaced by the ULOQ. LLOQ was 13 IU/mL for RSV-A and 10 IU/mL for RSV-B. ULOQ was 259061 IU/mL for RSV-A and 112476 IU/mL for RSV-B. 95% CI for GMFR (postinjection/baseline titers) was calculated based on the t-distribution of the differences in the log-transformed values between analysis timepoint and baseline, then back transformed to the original scale for presentation. PP Set included all randomized participants who received the study injection, complied with the immunogenicity testing schedule, had a Baseline and Day 29 assessment, and had no important protocol deviations that affected the immune response. 'n' = participants evaluable for specified categories.

End point type	Secondary
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End point timeframe:

Day 29 and Month 6

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The endpoint is reporting statistics for the specified arms only.

End point values	Part A Cohort 1: Placebo	Part A Cohort 1: mRNA-1345 Dose Level 1	Part A Cohort 1: mRNA-1345 Dose Level 2	Part A Cohort 1: mRNA-1345 Dose Level 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	38	41	39
Units: ratio				
geometric mean (confidence interval 95%)				
RSV-A: Day 29 (n=39,38,41,39)	0.84 (0.68 to 1.04)	11.86 (7.23 to 19.43)	5.90 (3.55 to 9.79)	12.69 (7.74 to 20.82)
RSV-A: Month 6 (n=33,34,35,38)	0.90 (0.57 to 1.40)	3.66 (2.41 to 5.56)	1.70 (0.95 to 3.05)	3.78 (2.33 to 6.13)
RSV-B: Day 29 (n=37,38,41,39)	0.81 (0.66 to 0.99)	7.31 (4.82 to 11.08)	4.27 (2.74 to 6.64)	8.85 (5.59 to 14.02)
RSV-B: Month 6 (n=33,34,35,38)	0.99 (0.65 to 1.53)	2.46 (1.72 to 3.52)	1.23 (0.74 to 2.04)	2.12 (1.30 to 3.45)

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Cohort 1): GMFR of Postbaseline/Baseline Binding Antibody Concentrations

End point title	Part A (Cohort 1): GMFR of Postbaseline/Baseline Binding Antibody Concentrations ^[8]
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End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ. Values greater than ULOQ were replaced by the ULOQ. LLOQ was 35 AU/mL and ULOQ was 580553 AU/mL for RSV Pre-F IgG antibody. 95% CI for GMFR (postinjection/baseline titers) was calculated based on the t-distribution of the differences in the log-transformed values between analysis timepoint and baseline, then back transformed to the original scale for presentation. PP Set included all randomized participants who received the study injection, complied with the immunogenicity testing schedule, had a Baseline and Day 29 assessment, and had no important protocol deviations that affected the immune response. 'Overall number of participants analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable for specified categories.

End point type	Secondary
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End point timeframe:

Day 29 and Month 6

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting statistics for the specified arms only.

End point values	Part A Cohort 1: Placebo	Part A Cohort 1: mRNA-1345 Dose Level 1	Part A Cohort 1: mRNA-1345 Dose Level 2	Part A Cohort 1: mRNA-1345 Dose Level 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	36	39	39
Units: ratio				
geometric mean (confidence interval 95%)				
Day 29 (n=38,36,39,39)	0.94 (0.76 to 1.17)	13.43 (6.78 to 26.58)	6.63 (4.18 to 10.52)	10.16 (6.53 to 15.79)
Month 6 (n=32,32,35,38)	0.81 (0.48 to 1.37)	2.86 (1.68 to 4.87)	1.28 (0.81 to 2.05)	2.16 (1.41 to 3.33)

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Cohort 1): Percentage of Participants With Seroresponse in RSV Neutralizing Antibody

End point title	Part A (Cohort 1): Percentage of Participants With Seroresponse in RSV Neutralizing Antibody ^[9]
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End point description:

Seroresponse was defined as a change from below the LLOQ to equal or above 4 * LLOQ, or at least a 4-fold increase if baseline was equal to or above the LLOQ. PP Set included all randomized participants who received the study injection, complied with the immunogenicity testing schedule, had a Baseline and Day 29 assessment, and had no important protocol deviations that affected the immune response. 'n' = participants evaluable for specified categories.

End point type	Secondary
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End point timeframe:

Baseline to Day 29 and Month 6

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting statistics for the specified arms only.

End point values	Part A Cohort 1: Placebo	Part A Cohort 1: mRNA-1345 Dose Level 1	Part A Cohort 1: mRNA-1345 Dose Level 2	Part A Cohort 1: mRNA-1345 Dose Level 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	38	41	39
Units: percentage of participants				
number (confidence interval 95%)				
RSV-A: Day 29 (n=39,38,41,39)	2.6 (0.1 to 13.5)	78.9 (62.7 to 90.4)	46.3 (30.7 to 62.6)	79.5 (63.5 to 90.7)
RSV-A: Month 6 (n=33,34,35,38)	9.1 (1.9 to 24.3)	50.0 (32.4 to 67.6)	28.6 (14.6 to 46.3)	52.6 (35.8 to 69.0)
RSV-B: Day 29 (n=37,38,41,39)	0 (0.0 to 9.5)	63.2 (46.0 to 78.2)	48.8 (32.9 to 64.9)	71.8 (55.1 to 85.0)
RSV-B: Month 6 (n=33,34,35,38)	9.1 (1.9 to 24.3)	26.5 (12.9 to 44.4)	22.9 (10.4 to 40.1)	39.5 (24.0 to 56.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Cohort 1): Percentage of Participants With Seroresponse in RSV Pre-F Binding Antibody

End point title	Part A (Cohort 1): Percentage of Participants With Seroresponse in RSV Pre-F Binding Antibody ^[10]
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End point description:

Seroresponse was defined as a change from below the LLOQ to equal or above 4 * LLOQ, or at least a 4-fold increase if baseline was equal to or above the LLOQ. PP Set included all randomized participants who received the study injection, complied with the immunogenicity testing schedule, had a Baseline and Day 29 assessment, and had no important protocol deviations that affected the immune response. 'Overall number of participants analyzed' = participants evaluable for this endpoint. 'n' = participants evaluable for specified categories.

End point type	Secondary
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End point timeframe:

Baseline to Day 29 and Month 6

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The endpoint is reporting statistics for the specified arms only.

End point values	Part A Cohort 1: Placebo	Part A Cohort 1: mRNA-1345 Dose Level 1	Part A Cohort 1: mRNA-1345 Dose Level 2	Part A Cohort 1: mRNA-1345 Dose Level 3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	36	39	39
Units: percentage of participants				
number (confidence interval 95%)				
Day 29 (n=38,36,39,39)	2.6 (0.1 to 13.8)	75.0 (57.8 to 87.9)	53.8 (37.2 to 69.9)	74.4 (57.9 to 87.0)
Month 6 (n=32,32,35,38)	6.3 (0.8 to 20.8)	21.9 (9.3 to 40.0)	17.1 (6.6 to 33.6)	36.8 (21.8 to 54.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Cohort 2): GMT of Serum RSV Neutralizing Antibody

End point title	Part A (Cohort 2): GMT of Serum RSV Neutralizing Antibody ^[11]
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End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ. Values greater than the ULOQ were replaced by the ULOQ. LLOQ was 13 IU/mL for RSV-A and 15 IU/mL for RSV-B. ULOQ was 259061 IU/mL for RSV-A and 162163 IU/mL for RSV-B. 95% CI for GM value was calculated based on the t-distribution of the log-transformed values, then back transformed to the original scale for presentation.

PP Set included all randomized participants who received the study injection, complied with the immunogenicity testing schedule, had a Baseline and Day 29 assessment, and had no important protocol deviations that affected the immune response.

End point type	Secondary
End point timeframe:	
Day 1 and Day 29	

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The endpoint is reporting statistics for the specified arms only.

End point values	Part A Cohort 2: mRNA-1345 Dose Level 2	Part A Cohort 2: mRNA-1345 Dose Level 3	Part A Cohort 2: mRNA-1345 Dose Level 4	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	58	60	
Units: IU/mL				
geometric mean (confidence interval 95%)				
RSV-A: Day 1	1260.25 (943.55 to 1683.25)	1027.77 (749.05 to 1410.18)	1230.06 (946.64 to 1598.32)	
RSV-A: Day 29	10168.70 (7560.52 to 13676.63)	9011.13 (6239.70 to 13013.52)	19541.50 (15311.61 to 24939.91)	
RSV-B: Day 1	669.76 (506.07 to 886.40)	617.58 (449.58 to 848.35)	581.70 (463.11 to 730.66)	
RSV-B: Day 29	3105.78 (2498.97 to 3859.94)	3523.27 (2598.78 to 4776.66)	4782.51 (4006.02 to 5709.50)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Cohort 2): GMC of Serum RSV Pre-F Binding Antibody

End point title	Part A (Cohort 2): GMC of Serum RSV Pre-F Binding
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End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ. Values greater than ULOQ were replaced by the ULOQ. LLOQ was 35 AU/mL and ULOQ was 580553 AU/mL for RSV Pre-F IgG antibody. 95% CI for GM value was calculated based on the t-distribution of the log-transformed values, then back transformed to the original scale for presentation. PP Set included all randomized participants who received the study injection, complied with the immunogenicity testing schedule, had a Baseline and Day 29 assessment, and had no important protocol deviations that affected the immune response.

End point type	Secondary
End point timeframe:	
Day 1 and Day 29	

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The endpoint is reporting statistics for the specified arms only.

End point values	Part A Cohort 2: mRNA-1345 Dose Level 2	Part A Cohort 2: mRNA-1345 Dose Level 3	Part A Cohort 2: mRNA-1345 Dose Level 4	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	58	60	
Units: AU/mL				
geometric mean (confidence interval 95%)				
Day 1	11060.58 (8799.38 to 13902.85)	9556.54 (7002.35 to 13042.41)	11882.31 (10029.95 to 14076.78)	
Day 29	67394.60 (54544.98 to 83271.33)	69494.70 (55349.62 to 87254.68)	109004.49 (94312.25 to 125985.52)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Cohort 2): GMFR of Postbaseline/Baseline Neutralizing Antibody Titers

End point title	Part A (Cohort 2): GMFR of Postbaseline/Baseline Neutralizing Antibody Titers ^[13]
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End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ. Values greater than the ULOQ were replaced by the ULOQ. LLOQ was 13 IU/mL for RSV-A and 15 IU/mL for RSV-B. ULOQ was 259061 IU/mL for RSV-A and 162163 IU/mL for RSV-B. 95% CI for GMFR (postinjection/baseline titers) was calculated based on the t-distribution of the differences in the log-transformed values between analysis timepoint and baseline, then back transformed to the original scale for presentation. PP Set included all randomized participants who received the study injection, complied with the immunogenicity testing schedule, had a Baseline and Day 29 assessment, and had no important protocol deviations that affected the immune response.

End point type	Secondary
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End point timeframe:

Day 29

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The endpoint is reporting statistics for the specified arms only.

End point values	Part A Cohort 2: mRNA-1345 Dose Level 2	Part A Cohort 2: mRNA-1345 Dose Level 3	Part A Cohort 2: mRNA-1345 Dose Level 4	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	58	60	
Units: ratio				
geometric mean (confidence interval 95%)				
RSV-A	8.07 (6.17 to 10.55)	8.77 (6.26 to 12.28)	15.89 (11.92 to 21.18)	
RSV-B	4.64 (3.61 to 5.95)	5.71 (4.21 to 7.72)	8.22 (6.53 to 10.35)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Cohort 2): Percentage of Participants With Seroresponse in RSV Neutralizing Antibody

End point title	Part A (Cohort 2): Percentage of Participants With Seroresponse in RSV Neutralizing Antibody ^[14]
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End point description:

Seroresponse was defined as a change from below the LLOQ to equal or above 4 * LLOQ, or at least a 4-fold increase if baseline was equal to or above the LLOQ. PP Set included all randomized participants who received the study injection, complied with the immunogenicity testing schedule, had a Baseline and Day 29 assessment, and had no important protocol deviations that affected the immune response.

End point type	Secondary
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End point timeframe:

Baseline to Day 29

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The endpoint is reporting statistics for the specified arms only.

End point values	Part A Cohort 2: mRNA-1345 Dose Level 2	Part A Cohort 2: mRNA-1345 Dose Level 3	Part A Cohort 2: mRNA-1345 Dose Level 4	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	58	60	
Units: percentage of participants				
number (confidence interval 95%)				
RSV-A	76.3 (63.4 to 86.4)	75.9 (62.8 to 86.1)	86.7 (75.4 to 94.1)	
RSV-B	54.2 (40.8 to 67.3)	60.3 (46.6 to 73.0)	71.7 (58.6 to 82.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Cohort 2): GMFR of Postbaseline/Baseline Binding Antibody Concentrations

End point title	Part A (Cohort 2): GMFR of Postbaseline/Baseline Binding Antibody Concentrations ^[15]
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End point description:

Antibody values reported as below LLOQ were replaced by 0.5*LLOQ. Values greater than ULOQ were replaced by the ULOQ. LLOQ was 35 AU/mL and ULOQ was 580553 AU/mL for RSV Pre-F IgG antibody. 95% CI for GMFR (postinjection/baseline titers) was calculated based on the t-distribution of the differences in the log-transformed values between analysis timepoint and baseline, then back

transformed to the original scale for presentation. PP Set included all randomized participants who received the study injection, complied with the immunogenicity testing schedule, had a Baseline and Day 29 assessment, and had no important protocol deviations that affected the immune response. 'Overall number of participants analyzed' = participants evaluable for this endpoint.

End point type	Secondary
End point timeframe:	
Day 29	

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The endpoint is reporting statistics for the specified arms only.

End point values	Part A Cohort 2: mRNA-1345 Dose Level 2	Part A Cohort 2: mRNA-1345 Dose Level 3	Part A Cohort 2: mRNA-1345 Dose Level 4	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	58	60	
Units: ratio				
geometric mean (confidence interval 95%)	6.09 (4.77 to 7.78)	7.27 (5.43 to 9.73)	9.17 (7.65 to 10.99)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part A (Cohort 2): Percentage of Participants With Seroresponse in RSV Pre-F Binding Antibody

End point title	Part A (Cohort 2): Percentage of Participants With Seroresponse in RSV Pre-F Binding Antibody ^[16]
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End point description:

Seroresponse was defined as a change from below the LLOQ to equal or above 4 * LLOQ, or at least a 4-fold increase if baseline was equal to or above the LLOQ. PP Set included all randomized participants who received the study injection, complied with the immunogenicity testing schedule, had a Baseline and Day 29 assessment, and had no important protocol deviations that affected the immune response.

End point type	Secondary
End point timeframe:	
Baseline to Day 29	

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The endpoint is reporting statistics for the specified arms only.

End point values	Part A Cohort 2: mRNA-1345 Dose Level 2	Part A Cohort 2: mRNA-1345 Dose Level 3	Part A Cohort 2: mRNA-1345 Dose Level 4	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	58	60	
Units: percentage of participants				
number (confidence interval 95%)	69.5 (56.1 to 80.8)	74.1 (61.0 to 84.7)	88.3 (77.4 to 95.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part B (Cohort 1): Number of Participants With AESIs and SAEs

End point title	Part B (Cohort 1): Number of Participants With AESIs and SAEs
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End point description:

An AESI was an AE (serious or nonserious) of scientific and medical concern specific to the Sponsor’s product or program, for which ongoing monitoring and immediate notification by the Investigator to the Sponsor are required. An SAE was defined as any AE that resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in disability, was a congenital anomaly/birth defect, or was an important medical event. A summary of SAEs and all nonserious AEs ("Other"), regardless of causality, is located in the "Reported Adverse Events" section. Part B Cohort 1 Safety Set included all participants in the Part A Cohort 1 Safety Set who re-enrolled in Part B of the study.

End point type	Secondary
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End point timeframe:

Day 1 through Part B EOS (Month 6)

End point values	Part B Cohort 1: Received Placebo in Part A	Part B Cohort 1: Received mRNA-1345 Dose Level 1 in Part A	Part B Cohort 1: Received mRNA-1345 Dose Level 2 in Part A	Part B Cohort 1: Received mRNA-1345 Dose Level 3 in Part A
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	24	25	24
Units: participants				
AESIs	0	1	0	0
SAEs	0	0	1	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality, SAEs, AESIs, MAAEs, and AEs leading to study discontinuation: up to Month 6 (Parts A & B). Other (non-serious) AEs: up to 28 days after study injection, unless they met criteria for AESIs, MAAEs, or AEs led to study discontinuation.

Adverse event reporting additional description:

Part A Safety Set included all randomized participants who received the study intervention.

Part B Cohort 1 Safety Set included all participants in the Part A Cohort 1 Safety Set who re-enrolled in Part B of the study.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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Reporting groups

Reporting group title	Part A Cohort 1: mRNA-1345 Dose Level 1
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Reporting group description:

Participants received a single IM injection of mRNA-1345 at Dose Level 1 on Day 1.

Reporting group title	Part A Cohort 1: Placebo
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Reporting group description:

Participants received a single IM injection of placebo on Day 1.

Reporting group title	Part A Cohort 2: mRNA-1345 Dose Level 2
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Reporting group description:

Participants received a single IM injection of mRNA-1345 at Dose Level 2 on Day 1.

Reporting group title	Part A Cohort 1: mRNA-1345 Dose Level 3
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Reporting group description:

Participants received a single IM injection of mRNA-1345 at Dose Level 3 on Day 1.

Reporting group title	Part A Cohort 1: mRNA-1345 Dose Level 2
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Reporting group description:

Participants received a single IM injection of mRNA-1345 at Dose Level 2 on Day 1.

Reporting group title	Part A Cohort 2: mRNA-1345 Dose Level 3
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Reporting group description:

Participants received a single IM injection of mRNA-1345 at Dose Level 3 on Day 1.

Reporting group title	Part A Cohort 2: mRNA-1345 Dose Level 4
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Reporting group description:

Participants received a single IM injection of mRNA-1345 at Dose Level 4 on Day 1.

Reporting group title	Part B Cohort 1: Received Placebo in Part A
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Reporting group description:

Participants who received placebo in Part A were followed up for safety assessment (for up to 6 months) in Part B. Participants did not receive any study drug in Part B.

Reporting group title	Part B Cohort 1: Received mRNA-1345 Dose Level 1 in Part A
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Reporting group description:

Participants who received mRNA-1345 at Dose Level 1 in Part A were followed up for safety assessment (for up to 6 months) in Part B. Participants did not receive any study drug in Part B.

Reporting group title	Part B Cohort 1: Received mRNA-1345 Dose Level 2 in Part A
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Reporting group description:

Participants who received mRNA-1345 at Dose Level 2 in Part A were followed up for safety assessment (for up to 6 months) in Part B. Participants did not receive any study drug in Part B.

Reporting group title	Part B Cohort 1: Received mRNA-1345 Dose Level 3 in Part A
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Reporting group description:

Participants who received mRNA-1345 at Dose Level 3 in Part A were followed up for safety assessment

Serious adverse events	Part A Cohort 1: mRNA-1345 Dose Level 1	Part A Cohort 1: Placebo	Part A Cohort 2: mRNA-1345 Dose Level 2
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 39 (0.00%)	0 / 41 (0.00%)	0 / 61 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	0 / 41 (0.00%)	0 / 61 (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	Additional description: Both participants had a prior history of asthma.		
subjects affected / exposed	0 / 39 (0.00%)	0 / 41 (0.00%)	0 / 61 (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
Infections and infestations			
Influenza			
subjects affected / exposed	0 / 39 (0.00%)	0 / 41 (0.00%)	0 / 61 (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	Part A Cohort 1: mRNA-1345 Dose Level 3	Part A Cohort 1: mRNA-1345 Dose Level 2	Part A Cohort 2: mRNA-1345 Dose Level 3
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	0 / 61 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Post procedural haemorrhage			

subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	0 / 61 (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	Additional description: Both participants had a prior history of asthma.		
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	0 / 61 (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
Infections and infestations			
Influenza			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	0 / 61 (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	Part A Cohort 2: mRNA-1345 Dose Level 4	Part B Cohort 1: Received Placebo in Part A	Part B Cohort 1: Received mRNA-1345 Dose Level 1 in Part A
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 62 (4.84%)	0 / 19 (0.00%)	0 / 24 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	1 / 62 (1.61%)	0 / 19 (0.00%)	0 / 24 (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
Respiratory, thoracic and mediastinal disorders			
Asthma	Additional description: Both participants had a prior history of asthma.		
subjects affected / exposed	2 / 62 (3.23%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Influenza			

subjects affected / exposed	0 / 62 (0.00%)	0 / 19 (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

Serious adverse events	Part B Cohort 1: Received mRNA-1345 Dose Level 2 in Part A	Part B Cohort 1: Received mRNA-1345 Dose Level 3 in Part A	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 25 (4.00%)	0 / 24 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 25 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asthma	Additional description: Both participants had a prior history of asthma.		
subjects affected / exposed	0 / 25 (0.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Influenza			
subjects affected / exposed	1 / 25 (4.00%)	0 / 24 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Part A Cohort 1: mRNA-1345 Dose Level 1	Part A Cohort 1: Placebo	Part A Cohort 2: mRNA-1345 Dose Level 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 39 (7.69%)	1 / 41 (2.44%)	5 / 61 (8.20%)
Infections and infestations			
Gastroenteritis viral			

subjects affected / exposed	2 / 39 (5.13%)	0 / 41 (0.00%)	1 / 61 (1.64%)
occurrences (all)	2	0	1
Pharyngitis streptococcal			
subjects affected / exposed	0 / 39 (0.00%)	0 / 41 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 39 (2.56%)	1 / 41 (2.44%)	3 / 61 (4.92%)
occurrences (all)	1	1	3

Non-serious adverse events	Part A Cohort 1: mRNA-1345 Dose Level 3	Part A Cohort 1: mRNA-1345 Dose Level 2	Part A Cohort 2: mRNA-1345 Dose Level 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 41 (17.07%)	1 / 41 (2.44%)	0 / 61 (0.00%)
Infections and infestations			
Gastroenteritis viral			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	3 / 41 (7.32%)	1 / 41 (2.44%)	0 / 61 (0.00%)
occurrences (all)	5	1	0
Upper respiratory tract infection			
subjects affected / exposed	4 / 41 (9.76%)	0 / 41 (0.00%)	0 / 61 (0.00%)
occurrences (all)	4	0	0

Non-serious adverse events	Part A Cohort 2: mRNA-1345 Dose Level 4	Part B Cohort 1: Received Placebo in Part A	Part B Cohort 1: Received mRNA- 1345 Dose Level 1 in Part A
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 62 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
Infections and infestations			
Gastroenteritis viral			
subjects affected / exposed	0 / 62 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 62 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	0 / 62 (0.00%)	0 / 19 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B Cohort 1: Received mRNA- 1345 Dose Level 2 in Part A	Part B Cohort 1: Received mRNA- 1345 Dose Level 3 in Part A	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	0 / 24 (0.00%)	
Infections and infestations			
Gastroenteritis viral			
subjects affected / exposed	0 / 25 (0.00%)	0 / 24 (0.00%)	
occurrences (all)	0	0	
Pharyngitis streptococcal			
subjects affected / exposed	0 / 25 (0.00%)	0 / 24 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 24 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 June 2024	Amendment included following changes: Cohort 3 was added to test a single dose of mRNA-1345 Dose Level 4 in participants aged 2 to <5 years of age for further dose ranging.
02 October 2024	Amendment included following changes: Cohort 3 was removed from Part A and Cohort 1 Part B was added to include safety follow-up and RSV surveillance during the next RSV season for participants 2 to <5 years of age who were previously enrolled and received a study injection in Cohort 1 of Part A.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
07 August 2024	A United States Food and Drug Administration (US FDA)-requested clinical hold applied for participants RSV-seronegative aged 2 to <5 years. Enrollment had been completed prior to the hold effective date	-

Notes:

Limitations and caveats

None reported