



Clinical trial results:

A Phase 4, Randomized, Observer-blind, Placebo-controlled, Crossover Study to Assess Cardiac Troponin Levels After mRNA-1273.712 Vaccine in Participants 12 Through 30 Years of Age

Summary

EudraCT number	2025-000442-25
Trial protocol	Outside EU/EEA
Global end of trial date	04 April 2025

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	mRNA-1273-P404
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT06634797
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	04 April 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 April 2025
Global end of trial reached?	Yes
Global end of trial date	04 April 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to assess cardiac troponin I (cTnI) values in participants who received mRNA-1273.712 or placebo.

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 on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, and other applicable laws and regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 October 2024
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects**Subjects enrolled per country**

Country: Number of subjects enrolled	United States: 1000
Worldwide total number of subjects	1000
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)	0
Adolescents (12-17 years)	450
Adults (18-64 years)	550
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants were randomized in a 1:1 ratio (500 participants in each injection sequence) to receive 2 study injections (mRNA-1273.712 and placebo) in a crossover design.

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	Subject, Investigator, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Sequence 1: mRNA-1273.712 Then Placebo

Arm description:

Participants received mRNA-1273.712 as an intramuscular (IM) injection on Day 1 of the study. Participants then received placebo matched to mRNA-1273.712 as an IM injection on Day 29 of the study.

Arm type	Experimental
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 was administered per schedule specified in the arm description.

Investigational medicinal product name	mRNA-1273.712
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dispersion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273.712 was administered per schedule specified in the arm description.

Arm title	Sequence 2: Placebo Then mRNA-1273.712
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Arm description:

Participants received placebo matched to mRNA-1273.712 as an IM injection on Day 1 of the study. Participants then received mRNA-1273.712 as an IM injection on Day 29 of the study.

Arm type	Experimental
Investigational medicinal product name	mRNA-1273.712
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dispersion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

mRNA-1273.712 was administered per schedule specified in the arm description.

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 was administered per schedule specified in the arm description.

Number of subjects in period 1	Sequence 1: mRNA-1273.712 Then Placebo	Sequence 2: Placebo Then mRNA-1273.712
Started	500	500
Received Study Vaccination	500	497
Completed	438	424
Not completed	62	76
Consent withdrawn by subject	12	21
Physician decision	3	3
Adverse event, non-fatal	-	1
Other than specified	1	1
Screen failure	-	2
Lost to follow-up	46	48

Baseline characteristics

Reporting groups

Reporting group title	Sequence 1: mRNA-1273.712 Then Placebo
Reporting group description:	
Participants received mRNA-1273.712 as an intramuscular (IM) injection on Day 1 of the study. Participants then received placebo matched to mRNA-1273.712 as an IM injection on Day 29 of the study.	
Reporting group title	Sequence 2: Placebo Then mRNA-1273.712
Reporting group description:	
Participants received placebo matched to mRNA-1273.712 as an IM injection on Day 1 of the study. Participants then received mRNA-1273.712 as an IM injection on Day 29 of the study.	

Reporting group values	Sequence 1: mRNA-1273.712 Then Placebo	Sequence 2: Placebo Then mRNA-1273.712	Total
Number of subjects	500	500	1000
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)	0	0	0
Adolescents (12-17 years)	235	215	450
Adults (18-64 years)	265	285	550
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	19.7	20.0	-
standard deviation	± 5.73	± 5.71	-
Gender Categorical			
Units: Subjects			
Female	266	272	538
Male	234	228	462
Race			
Units: Subjects			
White	320	334	654
Black or African American	132	108	240
Asian	19	14	33
American Indian or Alaska Native	1	3	4
Native Hawaiian or Other Pacific Islander	1	1	2
Multiple	21	30	51
Other	3	7	10
Not Reported	3	3	6
Ethnicity			
Units: Subjects			
Hispanic or Latino	68	79	147

Not Hispanic or Latino	423	417	840
Not Reported	8	4	12
Unknown	1	0	1

End points

End points reporting groups

Reporting group title	Sequence 1: mRNA-1273.712 Then Placebo
Reporting group description: Participants received mRNA-1273.712 as an intramuscular (IM) injection on Day 1 of the study. Participants then received placebo matched to mRNA-1273.712 as an IM injection on Day 29 of the study.	
Reporting group title	Sequence 2: Placebo Then mRNA-1273.712
Reporting group description: Participants received placebo matched to mRNA-1273.712 as an IM injection on Day 1 of the study. Participants then received mRNA-1273.712 as an IM injection on Day 29 of the study.	
Subject analysis set title	mRNA-1273.712
Subject analysis set type	Modified intention-to-treat
Subject analysis set description: Participants received mRNA-1273.712 as an IM injection on either Day 1 in Sequence 1 (mRNA-1273.712 – placebo) or Day 29 in Sequence 2 (placebo - mRNA-1273.712) of the study.	
Subject analysis set title	Placebo
Subject analysis set type	Modified intention-to-treat
Subject analysis set description: Participants received placebo matched to mRNA-1273.712 as an IM injection on either Day 1 in Sequence 2 (placebo - mRNA-1273.712) or Day 29 in Sequence 1 (mRNA-1273.712 – placebo) of the study.	
Subject analysis set title	Sequence 1 (mRNA-1273.712 – Placebo): mRNA-1273.712
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received mRNA-1273.712 as an IM injection on Day 1 in Sequence 1 of the study.	
Subject analysis set title	Sequence 1 (mRNA-1273.712 – Placebo): Placebo
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received placebo matching mRNA-1273.712 as an IM injection on Day 29 in Sequence 1 of the study.	
Subject analysis set title	Sequence 2 (Placebo – mRNA-1273.712): Placebo
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received placebo matched to mRNA-1273.712 as an IM injection on Day 1 in Sequence 2 of the study.	
Subject analysis set title	Sequence 2 (Placebo – mRNA-1273.712): mRNA-1273.712
Subject analysis set type	Safety analysis
Subject analysis set description: Participants received mRNA-1273.712 as an IM injection on Day 29 in Sequence 2 of the study.	

Primary: Number of Participants with Elevated cTnI at Day 4 or Day 32 (3 days After Injection 1 or Injection 2)

End point title	Number of Participants with Elevated cTnI at Day 4 or Day 32 (3 days After Injection 1 or Injection 2) ^[1]
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End point description:

Elevated cTnI was defined as >53.53 picograms per milliliter (pg/mL) in males and >38.64 pg/mL in females.

Evaluable Set: All randomized participants who received at least 1 study injection who had no major protocol deviations or conditions/medications that impacted critical or key analysis data. The 'number of subjects analysed' includes the number of participants with normal cTnI at pre-injection at either Day 1 or Day 29 and non-missing cTnI at both pre-injection and 3 days after any injection. One participant who was included in the analysis, had an elevation of cTnI pre-injection of study intervention on Day 1

and had a normal value of cTnI pre-injection of study intervention on Day 29. Note that other factors such as physical activity can affect cTnI.

End point type	Primary
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End point timeframe:

Day 4 and Day 32

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: No comparative statistical analyses were planned for this endpoint.

End point values	mRNA-1273.712	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	890	910		
Units: participants	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Elevated cTnI Level at Day 29 or Day 57 (28 Days After Injection 1 or Injection 2)

End point title	Number of Participants with Elevated cTnI Level at Day 29 or Day 57 (28 Days After Injection 1 or Injection 2)
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End point description:

Elevated cTnI was defined as >53.53 pg/mL in males and >38.64 pg/mL in females.

Evaluable Set: All randomized participants who received at least 1 study injection who had no major protocol deviations or conditions/medications that impacted critical or key analysis data. The 'number of subjects analysed' includes the number of participants with normal cTnI at pre-injection and non-missing cTnI at both pre-injection and 28 days after any injection.

End point type	Secondary
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End point timeframe:

Day 29 and Day 57

End point values	mRNA-1273.712	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	858	853		
Units: participants	4	8		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Serious Adverse Events (SAEs), Medically-attended Adverse Events (MAAEs), Adverse Events of Special Interest (AESIs), and

Adverse Events Leading to Withdrawal

End point title	Number of Participants with Serious Adverse Events (SAEs), Medically-attended Adverse Events (MAAEs), Adverse Events of Special Interest (AESIs), and Adverse Events Leading to Withdrawal
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End point description:

An adverse event (AE) was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention.

An SAE was defined as any AE that resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in birth defects or was an important medical event.

A MAAE was defined as an AE that led to an unscheduled visit to a healthcare practitioner.

Investigators reported AEs as AESIs based on pre-defined criteria. All suspected cases of cardiomyopathy and non-infectious myocarditis, pericarditis, and myopericarditis were reported as AESIs.

A summary of all Serious Adverse Events and Other Adverse Events (nonserious) regardless of causality is located in the 'Reported Adverse Events' Section. Safety Set: All randomized participants who received at least 1 study injection.

End point type	Secondary
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End point timeframe:

Day 1 up to Day 57

End point values	Sequence 1 (mRNA-1273.712 – Placebo): mRNA-1273.712	Sequence 1 (mRNA-1273.712 – Placebo): Placebo	Sequence 2 (Placebo – mRNA-1273.712): Placebo	Sequence 2 (Placebo – mRNA-1273.712): mRNA-1273.712
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	500	460	497	454
Units: participants				
SAEs	0	0	0	1
MAAEs	6	5	9	10
AESIs	1	1	0	0
AEs Leading to Study Discontinuation	0	0	1	0
AEs Leading to Discontinuation of Study Injection	1	0	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Elevated cTnI Level at Day 1 (Baseline)

End point title	Number of Participants with Elevated cTnI Level at Day 1 (Baseline)
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End point description:

Elevated cTnI was defined as >53.53 pg/mL in males and >38.64 pg/mL in females.

Evaluable Set: All randomized participants who received at least 1 study injection who had no major

protocol deviations or conditions/medications that impacted critical or key analysis data. The 'number of subjects analysed' includes the number of participants with non-missing cTnI at Day 1.

End point type	Secondary
End point timeframe:	
Day 1	

End point values	Sequence 1: mRNA- 1273.712 Then Placebo	Sequence 2: Placebo Then mRNA- 1273.712		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	491	489		
Units: participants	2	5		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Day 1 up to Day 57

Adverse event reporting additional description:

Safety Set: All randomized participants who received at least 1 dose of study injection. Data are presented by study intervention sequence, and treatment received.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.1
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Reporting groups

Reporting group title	mRNA-1273.712 – Placebo Sequence: mRNA-1273.712
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Reporting group description:

Participants received mRNA-1273.712 as an intramuscular injection on Day 1 of the study.

Reporting group title	mRNA-1273.712 – Placebo Sequence: Placebo
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Reporting group description:

Participants received placebo matching mRNA-1273.712 as an intramuscular injection on Day 29 of the study.

Reporting group title	Placebo – mRNA-1273.712 Sequence: Placebo
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Reporting group description:

Participants received placebo matching mRNA-1273.712 as an intramuscular injection on Day 1 of the study.

Reporting group title	Placebo – mRNA-1273.712: mRNA-1273.712
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Reporting group description:

Participants received mRNA-1273.712 as an intramuscular injection on Day 29 of the study.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: There were no non-serious adverse events reported above the 5% threshold.

Serious adverse events	mRNA-1273.712 – Placebo Sequence: mRNA-1273.712	mRNA-1273.712 – Placebo Sequence: Placebo	Placebo – mRNA-1273.712 Sequence: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 500 (0.00%)	0 / 460 (0.00%)	0 / 497 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Psychiatric disorders			
Suicidal Ideation			
subjects affected / exposed	0 / 500 (0.00%)	0 / 460 (0.00%)	0 / 497 (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	Placebo – mRNA-1273.712: mRNA-1273.712		
Total subjects affected by serious adverse events			

subjects affected / exposed	1 / 454 (0.22%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Psychiatric disorders			
Suicidal Ideation			
subjects affected / exposed	1 / 454 (0.22%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	mRNA-1273.712 – Placebo Sequence: mRNA-1273.712	mRNA-1273.712 – Placebo Sequence: Placebo	Placebo – mRNA- 1273.712 Sequence: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 500 (0.00%)	0 / 460 (0.00%)	0 / 497 (0.00%)

Non-serious adverse events	Placebo – mRNA- 1273.712: mRNA- 1273.712		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 454 (0.00%)		

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