Footnote 11

Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 COVID-19 Vaccine in Adults Aged 18 Years and Older

ClinicalTrials.gov Identifier: NCT04405076

Recruitment Status : Recruiting
First Posted : May 28, 2020
Last Update Posted : May 28, 2020

See **Contacts and Locations**

Sponsor:
ModernaTX, Inc.

Collaborator:
Biomedical Advanced Research and Development Authority

Information provided by (Responsible Party):
ModernaTX, Inc.

Study Description

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Brief Summary:
This clinical study will assess the safety, reactogenicity, and immunogenicity of 2 dose levels of **mRNA-1273** SARS-COV-2 vaccine in adults 18 years of age or older.

Condition or disease	Intervention/treatment	Phase
SARS-CoV-2	Biological: Biological: **mRNA-1273**: 50 mcg Other: Placebo Biological: Biological: **mRNA-1273**: 100 mcg	Phase 2

Study Design

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Study Type :
Interventional (Clinical Trial)

Estimated Enrollment :
600 participants

Allocation:
Randomized

Intervention Model:
Sequential Assignment

Masking:
Double (Participant, Investigator)

Masking Description:
Observer-blind

Primary Purpose:
Prevention

Official Title:
A Phase 2a, Randomized, Observer-Blind, Placebo Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of **mRNA-1273** SARS-COV-2 Vaccine in Adults Aged 18 Years and Older

Estimated Study Start Date :
May 25, 2020

Estimated Primary Completion Date :
March 2021

Estimated Study Completion Date :

August 2021

Arms and Interventions

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Arm	Intervention/treatment
Experimental: **mRNA-1273**: Dose 50 mcg - Adults Aged 18-54 Groups: Adults aged 18-54 years Dose: 50 mcg Intervention: Biological/Vaccine: **mRNA-1273** 50 mcg	Biological: Biological: **mRNA-1273**: 50 mcg Biological: **mRNA-1273**: 50 mcg Other Name: 50 mcg Other: Placebo Placebo: Saline Other Name: Saline
Experimental: **mRNA-1273**: Dose 50 mcg - Adults Aged 55+ years Groups: Adults aged 55+ years Dose: 50 mcg Intervention: Biological/Vaccine: **mRNA-1273** 50 mcg	Biological: Biological: **mRNA-1273**: 50 mcg Biological: **mRNA-1273**: 50 mcg Other Name: 50 mcg Other: Placebo Placebo: Saline Other Name: Saline
Experimental: **mRNA-1273**: Dose 100 mcg - Adults Aged 18-54 Groups: Adults aged 18-54 years Dose: 100 mcg Intervention: Biological/Vaccine: **mRNA-1273** 100 mcg	Other: Placebo Placebo: Saline Other Name: Saline Biological: Biological: **mRNA-1273**: 100 mcg Biological: **mRNA-1273**: 100 mcg Other Name: 100 mcg

Arm	Intervention/treatment
Experimental: **mRNA-1273**: Dose 100 mcg - Adults Aged 55+ years Groups: Adults aged 55+ years Dose: 100 mcg Intervention: Biological/Vaccine: **mRNA-1273** 100 mcg	Other: Placebo Placebo: Saline Other Name: Saline Biological: Biological: **mRNA-1273**: 100 mcg Biological: **mRNA-1273**: 100 mcg Other Name: 100 mcg

Outcome Measures

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Primary Outcome Measures :

1. Solicited local and systemic adverse reactions (ARs) [Time Frame: 7 days post-vaccination]
2. Unsolicited adverse events (AEs) [Time Frame: 28 days post-vaccination]
3. Medically-attended adverse events (MAAEs) [Time Frame: Month 0 through Month 13]
4. Serious adverse events (SAEs) [Time Frame: Month 0 through Month 13]
5. Change in the measure of clinical safety laboratory values in Cohort 2 from baseline [Time Frame: Through 1 month after last vaccination]
6. The number and percentage of participants with abnormalities in blood pressure, temperature, HR or respiratory rate will be assessed. [Time Frame: Through 1 year after last vaccination]
7. The number and percentage of participants with abnormalities in physical examinations will be assessed [Time Frame: Through 1 year after last vaccination]
8. Evaluate immunogenicity of **mRNA-1273** by titer of SARS-CoV-2-specific binding antibody (bAb) measured by enzyme-linked immunosorbent assay (ELISA) [Time Frame: Through 1 year after the final dose]

Secondary Outcome Measures :

1. Titer of SARS-CoV-2-specific neutralizing antibody (nAb) [Time Frame: Through 1 year post last vaccination]
2. Seroconversion as measured by an increase of SARS-CoV-2-specific neutralizing antibody (nAb) titer [Time Frame: Through 1 year post last vaccination]

   Seroconversion as measured by an increase of SARS-CoV-2-specific neutralizing antibody (nAb) titer either from below the limit of detection (LOD) or lower limit of quantification (LLOQ) to equal to or above LOD or LLOQ, or a 4-times higher titer in participants with pre-existing nAb titers.

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

Yes

Criteria

Inclusion Criteria:

Each participant must meet all of the following criteria during the screening period and at Day 1, unless noted otherwise, to be enrolled in this study:

1. Male or female, 18 years of age or older at the time of consent (Screening Visit, Day 0).
2. Understands and agrees to comply with the study procedures and provides written informed consent.
3. According to the assessment of the investigator, is in good general health and can comply with study procedures.
4. Body mass index (BMI) of 18 kg/m2 to 30 kg/m2 (inclusive) at the Screening Visit (Day 0).
5. Female participants of nonchildbearing potential may be enrolled in the study. Nonchildbearing potential is defined as surgically sterile (history of bilateral tubal ligation, bilateral oophorectomy, hysterectomy) or postmenopausal (defined as amenorrhea for ≥ 12 consecutive months prior to Screening (Day 0) without an alternative medical cause). A follicle-stimulating hormone (FSH) level may be measured at the discretion of the investigator to confirm postmenopausal status.
6. Female participants of childbearing potential may be enrolled in the study if the participant fulfills all the following criteria:

- Has a negative pregnancy test at Screening (Day 0) and on the day of the first injection (Day 1).
- Has practiced adequate contraception or has abstained from all activities that could result in pregnancy for at least 28 days prior to the first injection (Day 1).
- Has agreed to continue adequate contraception through 3 months following the second injection (Day 29).
- Is not currently breastfeeding.

Adequate female contraception is defined as consistent and correct use of a Food and Drug Administration (FDA) approved contraceptive method in accordance with the product label. For example:

- Barrier method (such as condoms, diaphragm, or cervical cap) used in conjunction with spermicide
- Intrauterine device
- Prescription hormonal contraceptive taken or administered via oral (pill), transdermal (patch), subdermal, or IM route
- Sterilization of a female participant's monogamous male partner prior to entry into the study Note: periodic abstinence (eg, calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception.

7. Male participants engaging in activity that could result in pregnancy of sexual partners must agree to practice adequate contraception from the time of the first injection and through 3 months after the last injection.

Adequate contraception for male participants is defined as:

- Monogamous relationship with a female partner using an intrauterine device or hormonal contraception (described above)
- Use of barrier methods and spermicide
- History of surgical sterilization
- Male participants with partners who have become pregnant prior to Screening are eligible to participate in the study.

Exclusion Criteria:

Participants meeting any of the following criteria at the Screening Visit (Day 0) or at Day 1, unless noted otherwise, will be excluded from the study:

1. Known history of SARS-CoV-2 infection or known exposure to someone with SARS CoV 2 infection or COVID-19.
2. Travel outside of the US in the 28 days prior to the Screening Visit (Day 0).
3. Pregnant or breastfeeding.
4. Is acutely ill or febrile 24 hours prior to or at the Screening Visit (Day 0). Fever is defined as a body temperature ≥ 38.0°C/100.4°F. Participants meeting this criterion may be rescheduled within the relevant

window periods. Afebrile participants with minor illnesses can be enrolled at the discretion of the investigator.

5. Prior administration of an investigational CoV (eg, SARS-CoV-2, SARS-CoV, MERS-CoV) vaccine.
6. Current treatment with investigational agents for prophylaxis against COVID-19.
7. Has a medical, psychiatric, or occupational condition that may pose additional risk as a result of participation, or that could interfere with safety assessments or interpretation of results according to the investigator's judgment.
8. Is a healthcare worker or a member of an emergency response team.
9. Current use of any inhaled substance (eg, tobacco or cannabis smoke, nicotine vapors).
10. History of chronic smoking (≥ 1 cigarette a day) within 1 year of the Screening Visit (Day 0).
11. History of illegal substance use or alcohol abuse within the past 2 years. This exclusion does not apply to historical cannabis use that was formerly illegal in the participant's state but is legal at the time of Screening.
12. Known history of hypertension, or systolic blood pressure > 150 mm Hg in participants in Cohort 1 (≥ 18 to < 55 years old) or systolic blood pressure > 160 mm Hg in participants in Cohort 2 (≥ 55 years old) at the Screening Visit (Day 0)..
13. Known history of hypotension or systolic blood pressure < 85 mm Hg at the Screening Visit (Day 0).
14. Diabetes mellitus
15. Diagnosis of chronic pulmonary disease (eg, chronic obstructive pulmonary disease, asthma)
16. Chronic cardiovascular disease
17. Resides in a nursing home
18. Grade 1 or higher toxicity on clinical safety laboratory testing at the Screening Visit (Day 0)
19. Current or previous diagnosis of immunocompromising condition, immune-mediated disease, or other immunosuppressive condition.
20. Received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to the Screening Visit (Day 0) (for corticosteroids ≥ 20 mg/day of prednisone equivalent). Topical tacrolimus is allowed if not used within 14 days prior to the Screening Visit (Day 0).
21. Anticipating the need for immunosuppressive treatment at any time during participation in the study.
22. Positive serology for hepatitis B virus surface antigen, hepatitis C virus antibody, or human immunodeficiency virus (HIV) type 1 or 2 antibodies identified at the Screening Visit (Day 0).
23. History of anaphylaxis, urticaria, or other significant AR requiring medical intervention after receipt of a vaccine.
24. Bleeding disorder considered a contraindication to IM injection or phlebotomy.
25. Diagnosis of malignancy within previous 10 years (excluding non-melanoma skin cancer).

26. Has received or plans to receive a licensed vaccine ≤ 28 days prior to the first injection (Day 1) or plans to receive a licensed vaccine within 28 days before or after any study injection. Licensed influenza vaccines may be received more than 14 days before or after any study injection.
27. Receipt of systemic immunoglobulins or blood products within 3 months prior to the Screening Visit (Day 0) or plans for receipt during the study.
28. Has donated ≥ 450 mL of blood products within 28 days prior to the Screening Visit (Day 0) or plans to donate blood products during the study.
29. Participated in an interventional clinical study within 28 days prior to the Screening Visit (Day 0) or plans to do so while participating in this study.
30. Is an immediate family member or household member of study personnel

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04405076***

Contacts

Contact: Moderna Clinical Trials 855-663-6762 clinicaltrials@modernatx.com

Locations

United States, Georgia

Meridian Clinical Research — **Recruiting**
Savannah, Georgia, United States, 31406
Contact 912-623-2240

United States, Kansas

Heartland Research Associates — **Recruiting**
Newton, Kansas, United States, 67114
Contact 316-283-2800

United States, Missouri

Heartland Research Associates — **Recruiting**

Kansas City, Missouri, United States, 64114
Contact 816-943-0770

United States, Nebraska

Meridian Clinical Research **Recruiting**
Norfolk, Nebraska, United States, 68701
Contact 402-371-0797

Meridian Clinical Research **Not yet recruiting**
Omaha, Nebraska, United States, 68134
Contact 402-934-7563

United States, North Carolina

Trial Management Associates **Recruiting**
Wilmington, North Carolina, United States, 28403
Contact 910-833-1954

United States, South Dakota

Meridian Clinical Research **Recruiting**
Dakota Dunes, South Dakota, United States, 57049
Contact 605-232-9000

United States, Texas

Benchmark Research **Recruiting**
Austin, Texas, United States, 78705
Contact 512-478-5416

Benchmark Research **Recruiting**
San Angelo, Texas, United States, 76904
Contact 325-716-1355

United States, Utah

Advanced Clinical Research/Velocity **Not yet recruiting**
West Jordan, Utah, United States, 84088
Contact 801-542-8190

Sponsors and Collaborators

ModernaTX, Inc.

Biomedical Advanced Research and Development Authority

More Information

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Responsible Party:

ModernaTX, Inc.

ClinicalTrials.gov Identifier:

NCT04405076 History of Changes

Other Study ID Numbers:

mRNA-1273-P201

75A50120C00034 (Other Grant/Funding Number: BARDA)

First Posted:

May 28, 2020 Key Record Dates

Last Update Posted:

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Last Verified:

May 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:

No

Studies a U.S. FDA-regulated Drug Product:

Yes

Studies a U.S. FDA-regulated Device Product:

No

Keywords provided by ModernaTX, Inc.:

mRNA-1273
mRNA-1273 vaccine
SARS-CoV-2
SARS-CoV-2 Vaccine
Coronavirus
Virus Diseases
Messenger RNA
COVID 19
COVID 19 Vaccine
Moderna