A Study to Evaluate the Safety, Reactogenicity, and Effectiveness of mRNA-1273 Vaccine in Adolescents 12 to <18 Years Old to Prevent COVID-19 (TeenCove)

ClinicalTrials.gov Identifier: NCT04649151

Recruitment Status : Recruiting
First Posted : December 2, 2020
Last Update Posted : February 16, 2021

See **Contacts and Locations**

Sponsor:
ModernaTX, Inc.

Collaborator:
Biomedical Advanced Research and Development Authority

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

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

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Brief Summary:
The mRNA-1273 vaccine is being developed to prevent COVID-19, the disease resulting from Severe Acute Respiratory Syndrome coronavirus (SARS-CoV-2) infection. The study is designed to primarily evaluate the safety and

reactogenicity of a single dose level of mRNA-1273 vaccine administered in 2 doses 28 days apart to an adolescent population.

Condition or disease	Intervention/treatment	Phase
SARS-CoV-2	Biological: mRNA-1273 Biological: Placebo	Phase 2 Phase 3

Detailed Description:
Please access http://TeenCoveStudy.com for additional information, such as Study Overview, Participation, Site Locations along with contact numbers for each location for the study.

Study Design

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Study Type :
Interventional (Clinical Trial)

Estimated Enrollment :
3000 participants

Allocation:
Randomized

Intervention Model:
Parallel Assignment

Masking:
Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose:
Prevention

Official Title:
A Phase 2/3, Randomized, Observer-Blind, Placebo Controlled Study to Evaluate the Safety, Reactogenicity, and Effectiveness of mRNA-1273 **SARS CoV 2** Vaccine in Healthy Adolescents 12 to <18 Years of Age

Actual Study Start Date :
December 9, 2020

Estimated Primary Completion Date :
June 30, 2022

Estimated Study Completion Date :
June 30, 2022

Arms and Interventions

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Arm	Intervention/treatment
Experimental: mRNA-1273 Participants will receive 1 intramuscular (IM) injection of 100 microgram (ug) mRNA-1273 on Day 1 and on Day 29.	Biological: mRNA-1273 Sterile liquid for injection
Placebo Comparator: Placebo Participants will receive 1 IM injection of mRNA-1273-matching placebo on Day 1 and on Day 29.	Biological: Placebo 0.9% sodium chloride (normal saline) injection

Outcome Measures

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Primary Outcome Measures :

1. Number of Participants with Solicited Local and Systemic Adverse Reactions (ARs) [Time Frame: Up to Day 8 (7 days after first dose) and up to Day 36 (7 days after second dose)]
2. Number of Participants with Unsolicited Adverse Events (AEs) [Time Frame: Up to Day 57 (28 days after each dose)]
3. Number of Participants with Serious Adverse Events (SAEs), Medically Attended AEs (MAAEs), or Adverse Events of Special Interest (AESI) [Time Frame: Up to Day 394 (1 year after second dose)]
4. Number of Participants Who have Reached the Acceptable Threshold for the Serum Ab Level at Day 57 [Time Frame: Day 57 (28 days after second dose)]

   Acceptable serum Ab threshold as predefined for the study.

5. Comparison of the Geometric Mean of the Serum Neutralizing Antibody (nAb) level against the Geometric Mean of the Serum nAb level in Study mRNA-1273-P301 (NCT04470427)
   [Time Frame: Day 57 (28 days after second dose)]

Secondary Outcome Measures :

1. Geometric Mean Value of SARS-CoV-2 Spike Protein (S2P)-specific binding antibody (bAb)
   [Time Frame: Day 1, Day 57 (1 month after dose 2), Day 209 (6 months after dose 2), and Day 394 (1 year after dose 2)]
2. Geometric Mean Value of SARS-CoV-2-specific nAb [Time Frame: Day 1, Day 57 (1 month after dose 2), Day 209 (6 months after dose 2), and Day 394 (1 year after dose 2)]
3. Number of Participants with a SARS-CoV-2 Infection Starting on Day 57 [Time Frame: Day 57 up to Day 394]

   Clinical signs indicative of SARS-CoV-2 infection as predefined for the study.

4. Number of Participants with a First Occurrence of COVID-19 Starting 14 days after Second Dose of mRNA-1273 or Placebo [Time Frame: Day 29 (second dose) up to Day 394 (1 year after second dose)]

   Clinical signs indicative of COVID-19 as predefined for the study.

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:

12 Years to 17 Years (Child)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

Yes

Criteria

Inclusion Criteria:

- Participants 12 to <18 years of age at the time of consent (Screening Visit, Day 0) who, in the opinion of the Investigator, are in good general health based on review of medical history and screening physical examination.
- Investigator assessment that the participant, in the case of an emancipated minor, or parent(s)/legally acceptable representative(s) [LAR(s)] understand and is willing and physically able to comply with protocol-mandated follow up, including all procedures and provides written informed consent/assent.
- Body mass index (BMI) at or above the third percentile according to World Health Organization (WHO) Child Growth Standards at the Screening Visit (Day 0)

- Female participants of nonchildbearing potential may be enrolled in the study. Nonchildbearing potential is defined as premenarche or surgically sterile (history of bilateral tubal ligation, bilateral oophorectomy, hysterectomy).
- Female participants of childbearing potential may be enrolled in the study if the participant has a negative pregnancy test at Screening (Day 0), on the day of the first injection (Day 1), and on the day of the second injection (Day 29); 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); and is not currently breastfeeding.

Exclusion Criteria:

- Known history of SARS-CoV-2 infection or known close contact with anyone with laboratory-confirmed SARS-CoV-2 infection or COVID-19 within 2 weeks prior to vaccine administration
- Travel outside of the United States in the 28 days prior to the Screening Visit (Day 0)
- Pregnant or breastfeeding
- 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°Celsius/≥100.4°Farenheit. Participants who meet this criterion may have visits rescheduled within the relevant study visit windows. Afebrile participants with minor illnesses can be enrolled at the discretion of the Investigator.
- Prior administration of an investigational coronavirus (for example, SARS-CoV, Middle East Respiratory Syndrome [MERS-CoV]) vaccine
- Current treatment with investigational agents for prophylaxis against COVID-19
- 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
- Current use of any inhaled substance (for example, tobacco or cannabis smoke, nicotine vapors)
- History of chronic smoking (≥1 cigarette a day) within 1 year of the Screening Visit (Day 0)
- 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.
- History of a diagnosis or condition that, in the judgment of the Investigator, may affect study endpoint assessment or compromise participant safety, specifically:
    - Congenital or acquired immunodeficiency, including human immunodeficiency virus (HIV) infection
    - Suspected active hepatitis
    - Has a bleeding disorder that is considered a contraindication to IM injection or phlebotomy
    - Dermatologic conditions that could affect local solicited adverse reaction (AR) assessments

- History of anaphylaxis, urticaria, or other significant AR requiring medical intervention after receipt of a vaccine
- Diagnosis of malignancy within the previous 10 years (excluding nonmelanoma skin cancer)
- Febrile seizures

- Receipt of:
  - Any licensed vaccine within 28 days before the first dose of investigational product (IP) or plans for receipt of any licensed vaccine through 28 days following the last dose of IP
  - Systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to the day of enrollment (for corticosteroids, ≥20 mg/day prednisone equivalent). Topical tacrolimus is allowed if not used within 14 days prior to the day of enrollment. Participants may have visits rescheduled for enrollment if they no longer meet this criterion within the Screening Visit window. Inhaled, nasal, and topical steroids are allowed.
  - Intravenous blood products (red cells, platelets, immunoglobulins) within 3 months prior to enrollment
- 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
- 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
- Is an immediate family member or has a household contact who is an employee of the research center or otherwise involved with the conduct of the study

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): ***NCT04649151***

Contacts

Contact: **Moderna** Clinical Trials 877-913-3286 clinicaltrials@moderna

Contact: See "Additional Information" below to access study website

Locations

Show 25 study locations

Sponsors and Collaborators

ModernaTX, Inc.

Biomedical Advanced Research and Development Authority

More Information

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Additional Information:

Click here to access the website, http://TeenCoveStudy.com, for additional information for the study, such as Study Overview, Participation, Site Locations, along with contact numbers for each location for the study.

Responsible Party:
ModernaTX, Inc.

ClinicalTrials.gov Identifier:
NCT04649151 History of Changes

Other Study ID Numbers:
mRNA-1273-P203

First Posted:
December 2, 2020 Key Record Dates

Last Update Posted:
February 16, 2021

Last Verified:
February 2021

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