A Study to Evaluate Efficacy, Safety, and Immunogenicity of mRNA-1273 Vaccine in Adults Aged 18 Years and Older to Prevent COVID-19

ClinicalTrials.gov Identifier: NCT04470427

Recruitment Status : Active, not recruiting
First Posted : July 14, 2020
Last Update Posted : June 10, 2021

Sponsor:
ModernaTX, Inc.

Collaborators:
Biomedical Advanced Research and Development Authority
National Institute of Allergy and Infectious Diseases (NIAID)

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

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 efficacy, safety, and immunogenicity of mRNA-1273 to prevent COVID-19 for up to 2 years after the second dose of mRNA-1273.

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

Detailed Description:

This is a 2-part Phase 3 study, with Part A (Blinded Phase) and Part B (Open-label Observational Phase). Participants in Part A are blinded to their treatment assignment, with participants receiving either 2 active mRNA-1273 vaccine doses or placebo. Part B of the study is designed to offer participants to be unblinded so that participants who received placebo in Part A can request 2 doses of open-label mRNA-1273 vaccine. Additionally, participants who choose to be unblinded and was only able to receive 1 dose of mRNA-1273 due to administrative reasons, can choose to receive the second dose of mRNA-1273 during Part B.

Please access www.modernatx.com/cove-study for additional information, such as Study Overview, Participation, and Site Locations along with contact numbers for each location for the study.

Study Design

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Study Type : Interventional (Clinical Trial)
Actual Enrollment : 30420 participants

Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Masking Description:	Part A is observer-blind. During Part B participants may request to be unblinded by scheduling a Participant Decision clinic visit.
Primary Purpose:	Prevention
Official Title:	A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older
Actual Study Start Date :	July 27, 2020
Estimated Primary Completion Date :	October 27, 2022
Estimated Study Completion Date :	October 27, 2022

Arms and Interventions

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Arm	Intervention/treatment
Experimental: mRNA-1273 Part A: Participants will receive 1 intramuscular (IM) injection of 100 microgram (ug) mRNA-1273 on Day 1 and on Day 29. Part B: Participants who choose to be unblinded and received mRNA-1273-matching placebo during Part A, will receive 1 IM injection of 100 ug mRNA-1273 on Day 1 and Day 29, if the participant chooses. Participants who choose to be unblinded and was only able to receive 1 dose of mRNA-1273 due to administrative reasons, will receive 1 IM injection of 100 ug mRNA-1273 on Day 1, if the participant chooses.	Biological: mRNA-1273 Sterile liquid for injection Biological: Placebo 0.9% sodium chloride (normal saline) injection