Phase III trial is set to complete for Pfizer on January 31, 2023 (https://clinicaltrials.gov/ct2/show/NCT04368728), Moderna on October 27, 2022 (https://clinicaltrials.gov/ct2/show/NCT04470427), and Johnson & Johnson on January 2, 2023 (https://clinicaltrials.gov/ct2/show/NCT04505722

Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT04368728
Recruitment Status : Active, not recruiting
First Posted : April 30, 2020
Last Update Posted : February 10, 2021
Sponsor:
BioNTech SE
Collaborator:
Pfizer
Information provided by (Responsible Party):
BioNTech SE

Study Details Tabular ViewNo Results PostedDisclaimerHow to Read a Study Record
Study Description
Go to sections
Brief Summary:
This is a Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection, and efficacy study in healthy individuals.
The study consists of 2 parts: Phase 1: to identify preferred vaccine candidate(s) and dose level(s); Phase 2/3: an expanded cohort and efficacy part.
The study will evaluate the safety, tolerability, and immunogenicity of 2 different SARS CoV 2 RNA vaccine candidates against COVID 19 and the efficacy of 1 candidate:
As a 2-dose (separated by 21 days) schedule;
At various different dose levels in Phase 1;
In 3 age groups (Phase 1: 18 to 55 years of age, 65 to 85 years of age; Phase 2/3: ≥12 years of age [stratified as 12-15, 16-55 or >55 years of age]).
The candidate selected for evaluation in Phase 2/3 is BNT162b2 (mid-dose).
Participants ≥16 years of age who originally received placebo will be offered the opportunity to receive BNT162b2 at defined points as part of the study.

Condition or disease Intervention/treatment Phase

SARS-CoV-2 Infection
COVID-19
Biological: BNT162b1
Biological: BNT162b2
Other: Placebo
Phase 2
Phase 3

Study Design
Go to sections
Study Type :
Interventional (Clinical Trial)
Estimated Enrollment :
43998 participants
Allocation:
Randomized
Intervention Model:
Parallel Assignment
Masking:
Triple (Participant, Care Provider, Investigator)
Primary Purpose:
Prevention
Official Title:
A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS
Actual Study Start Date :
April 29, 2020
Estimated Primary Completion Date :
August 3, 2021
Estimated Study Completion Date :
January 31, 2023
Arms and Interventions
Go to sections
Arm Intervention/treatment
Experimental: Low dose, 18-55 years of age (2 doses) Biological: BNT162b1
Intramuscular injection

Biological: BNT162b2
Intramuscular injection

Experimental: Low-mid dose, 18-55 years of age (2 doses) Biological: BNT162b1
Intramuscular injection

Biological: BNT162b2
Intramuscular injection

Experimental: Mid dose, 18-55 years of age (2 doses) Biological: BNT162b1
Intramuscular injection

Biological: BNT162b2
Intramuscular injection

Experimental: Low dose, 65-85 years of age (2 doses) Biological: BNT162b1
Intramuscular injection

Biological: BNT162b2
Intramuscular injection

Experimental: Low-mid dose, 65-85 years of age (2 doses) Biological: BNT162b1
Intramuscular injection

Biological: BNT162b2
Intramuscular injection

Experimental: Mid dose, 65-85 years of age (2 doses) Biological: BNT162b1
Intramuscular injection

Biological: BNT162b2
Intramuscular injection

Experimental: Mid dose, ≥12 years of age (2 doses) Biological: BNT162b2
Intramuscular injection

Placebo Comparator: Placebo, 18-55 years of age Other: Placebo
Intramuscular injection

Placebo Comparator: Placebo, 65-85 years of age Other: Placebo
Intramuscular injection

Placebo Comparator: Placebo, ≥12 years of age Other: Placebo
Intramuscular injection

Experimental: High dose, 18-55 years of age (2 doses) Biological: BNT162b1
Intramuscular injection

Vaccination of Placebo recipients with BNT162b2 - Stage 1

Participants ≥16 years of age who originally received placebo and are eligible for COVID-19 vaccination following any local or national recommendations will be offered the opportunity to receive BNT162b2 as part of the study.
Biological: BNT162b2
Intramuscular injection

Vaccination of placebo recipients with BNT162b2 - Stage 2
Participants ≥16 years of age who originally received placebo will be offered the opportunity to receive BNT162b2 at defined points as part of the study.
Biological: BNT162b2
Intramuscular injection

Outcome Measures
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Primary Outcome Measures :
Percentage of participants in Phase 1 reporting local reactions [Time Frame: For 7 days after dose 1 and dose 2]
Pain at the injection site, redness, and swelling as self-reported on electronic diaries.

Percentage of participants in Phase 1 reporting systemic events [Time Frame: For 7 days after dose 1 and dose 2]
Fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain as self-reported on electronic diaries.

Percentage of participants in Phase 1 reporting adverse events [Time Frame: From dose 1 through 1 month after the last dose]
As elicited by investigational site staff

Percentage of participants in Phase 1 reporting serious adverse events [Time Frame: From dose 1 through 6 months after the last dose]
As elicited by investigational site staff

Percentage of Phase 1 participants with abnormal hematology and chemistry laboratory values [Time Frame: 1 day after dose 1]
As measured at the central laboratory

Percentage of Phase 1 participants with abnormal hematology and chemistry laboratory values [Time Frame: 7 days after dose 1]
As measured at the central laboratory

Percentage of Phase 1 participants with abnormal hematology and chemistry laboratory values [Time Frame: 7 days after dose 2]
As measured at the central laboratory

Percentage of Phase 1 participants with grading shifts in hematology and chemistry laboratory assessments [Time Frame: Between baseline and 1 day after dose 1]
As measured at the central laboratory

Percentage of Phase 1 participants with grading shifts in hematology and chemistry laboratory assessments [Time Frame: Between baseline and 7 days after dose 1]
As measured at the central laboratory

Percentage of Phase 1 participants with grading shifts in hematology and chemistry laboratory assessments [Time Frame: Between before dose 2 and 7 days after dose 2]
As measured at the central laboratory

In the first 360 participants randomized into Phase 2/3, percentage of participants reporting local reactions [Time Frame: For 7 days after dose 1 and dose 2]
Pain at the injection site, redness, and swelling as self-reported on electronic diaries.

In the first 360 participants randomized into Phase 2/3, percentage of participants reporting systemic events [Time Frame: For 7 days after dose 1 and dose 2]
Fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain as self-reported on electronic diaries.

In the first 360 participants randomized into Phase 2/3, percentage of participants reporting adverse events [Time Frame: From dose 1 through 1 month after the last dose]
As elicited by investigational site staff

In the first 360 participants randomized into Phase 2/3, percentage of participants reporting serious adverse events [Time Frame: From dose 1 through 6 months after the last dose]
As elicited by investigational site staff

In a subset of at least 6000 participants randomized in Phase 2/3, percentage of participants reporting local reactions [Time Frame: For 7 days after dose 1 and dose 2]
Pain at the injection site, redness, and swelling as self-reported on electronic diaries.

In a subset of at least 6000 participants randomized in Phase 2/3, percentage of participants reporting systemic events [Time Frame: For 7 days after dose 1 and dose 2]
Fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain as self-reported on electronic diaries.

Percentage of participants in Phase 2/3 reporting adverse events [Time Frame: From dose 1 through 1 month after the last dose]

As elicited by investigational site staff

Percentage of participants in Phase 2/3 reporting serious adverse events [Time Frame: From dose 1 through 6 months after the last dose]
As elicited by investigational site staff

Confirmed COVID-19 in Phase 2/3 participants without evidence of infection before vaccination [Time Frame: From 7 days after the second dose of study intervention to the end of the study, up to 2 years]
Per 1000 person-years of follow-up

Confirmed COVID-19 in Phase 2/3 participants with and without evidence of infection before vaccination [Time Frame: From 7 days after the second dose of study intervention to the end of the study, up to 2 years]
Per 1000 person-years of follow-up

Percentage of participants 12-15 years of age in Phase 3 reporting adverse events [Time Frame: From dose 1 through 1 month after the last dose]
As elicited by investigational site staff

Percentage of participants 12-15 years of age in Phase 3 reporting adverse events [Time Frame: From dose 1 through 6 months after the last dose]
As elicited by investigational site staff

In participants 12-15 years of age randomized in Phase 3, percentage of participants reporting local reactions [Time Frame: For 7 days after dose 1 and dose 2]
Pain at the injection site, redness, and swelling as self-reported on electronic diaries.

In participants 12-15 years of age randomized in Phase 3, percentage of participants reporting systemic events [Time Frame: For 7 days after dose 1 and dose 2]
Fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain as self-reported on electronic diaries.

Secondary Outcome Measures :
In Phase 1 participants, SARS-CoV-2 serum neutralizing antibody levels, expressed as GMTs [Time Frame: Through 2 years after the final dose]
As measured at the central laboratory

In Phase 1 participants, GMFR in SARS-CoV-2 serum neutralizing titers from before vaccination to each subsequent time point [Time Frame: Through 2 years after the final dose]
As measured at the central laboratory

Proportion of participants in Phase 1 achieving a greater than or equal to 4-fold rise from before vaccination in SARS-CoV-2 serum neutralizing antibody levels [Time Frame: Through 2 years after the final dose]
As measured at the central laboratory

In Phase 1 participants, SARS-CoV-2 anti-S1 binding antibody levels and anti-RBD binding antibody levels, expressed as GMCs [Time Frame: Through 2 years after the final dose]
As measured at the central laboratory

Proportion of participants in Phase 1 achieving a greater than or equal to 4-fold rise from before vaccination in SARS-CoV-2 anti-S1 binding antibody levels and anti-RBD binding antibody levels [Time Frame: Through 2 years after the final dose]
As measured at the central laboratory

In Phase 1 participants, GMFR in SARS-CoV-2 anti-S1 binding antibody levels and anti-RBD binding antibody levels from before vaccination to each subsequent time point [Time Frame: Through 2 years after the final dose]
As measured at the central laboratory

In Phase 1 participants, GMR of the geometric mean of SARS-CoV-2 serum neutralizing titers to the geometric mean of SARS CoV 2 (anti-S1 and anti-RBD) binding antibody levels [Time Frame: Through 2 years after the final dose]
As measured at the central laboratory

Confirmed COVID-19 in Phase 2/3 participants without evidence of infection before vaccination [Time Frame: From 14 days after the second dose of study intervention to the end of the study, up to 2 years]
Per 1000 person-years of follow-up

Confirmed COVID-19 in Phase 2/3 participants with and without evidence of infection before vaccination [Time Frame: From 14 days after the second dose of study intervention to the end of the study, up to 2 years]
Per 1000 person-years of follow-up

Confirmed severe COVID-19 in Phase 2/3 participants without evidence of infection before vaccination [Time Frame: From 7 days after the second dose of study intervention to the end of the study, up to 2 years]
Per 1000 person-years of follow-up

Confirmed severe COVID-19 in Phase 2/3 participants without evidence of infection before vaccination [Time Frame: From 14 days after the second dose of study intervention to the end of the study, up to 2 years]
Per 1000 person-years of follow-up

Confirmed severe COVID-19 in Phase 2/3 participants with and without evidence of infection before vaccination [Time Frame: From 7 days after the second dose of study intervention to the end of the study, up to 2 years]
Per 1000 person-years of follow-up

Confirmed severe COVID-19 in Phase 2/3 participants with and without evidence of infection before vaccination [Time Frame: From 14 days after the second dose of study intervention to the end of the study, up to 2 years]
Per 1000 person-years of follow-up

Confirmed COVID-19 (according to the CDC-defined symptoms) in Phase 2/3 participants without evidence of infection before vaccination [Time Frame: From 7 days after the second dose of study intervention to the end of the study, up to 2 years]
Per 1000 person-years of follow-up

Confirmed COVID-19 (according to the CDC-defined symptoms) in Phase 2/3 participants without evidence of infection before vaccination [Time Frame: From 14 days after the second dose of study intervention to the end of the study, up to 2 years]
Per 1000 person-years of follow-up

Confirmed COVID-19 (according to the CDC-defined symptoms) in Phase 2/3 participants with and without evidence of infection before vaccination [Time Frame: From 7 days after the second dose of study intervention to the end of the study, up to 2 years]
Per 1000 person-years of follow-up

Confirmed COVID-19 (according to the CDC-defined symptoms) in Phase 2/3 participants with and without evidence of infection before vaccination [Time Frame: From 14 days after the second dose of study intervention to the end of the study, up to 2 years]
Per 1000 person-years of follow-up

GMR of SARS CoV 2 neutralizing titers in the 2 age groups (12-15 years of age to 16-25 years of age) [Time Frame: 1 month after the second dose]
As measured at the central laboratory

Incidence of asymptomatic SARS CoV-2 infection based on N binding antibody seroconversion in participants with no serological or virological evidence of past SARS CoV-2 infection or confirmed COVID-19 prior to 1 month after receipt of the second dose [Time Frame: Through 1 month after the second dose]
Per 1000 person-years of follow-up

Incidence of asymptomatic SARS CoV-2 infection based on central laboratory-confirmed NAAT in participants with no serological or virological evidence (up to the start of the asymptomatic surveillance period) of past SARS-CoV-2 infection [Time Frame: Through 6 months after the second dose]

Per 1000 person-years of follow-up

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 and older (Child, Adult, Older Adult)
Sexes Eligible for Study:
All
Accepts Healthy Volunteers:
Yes
Criteria
Inclusion Criteria:
Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or ≥12 years, inclusive, at randomization (dependent upon study phase). Note that participants <18 years of age cannot be enrolled in the EU.
Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures.
Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study.
Participants who, in the judgment of the investigator, are at risk for acquiring COVID-19.
Capable of giving personal signed informed consent
Exclusion Criteria:
Other medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study.
Phases 1 and 2 only: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).
History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s).
Receipt of medications intended to prevent COVID 19.
Previous clinical (based on COVID-19 symptoms/signs alone, if a SARS-CoV-2 NAAT result was not available) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID 19
Phase 1 only: Individuals at high risk for severe COVID-19, including those with any of the following risk factors:

Hypertension
Diabetes mellitus
Chronic pulmonary disease
Asthma
Current vaping or smoking
History of chronic smoking within the prior year
BMI >30 kg/m2
Anticipating the need for immunosuppressive treatment within the next 6 months
Phase 1 only: Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel).
Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination.
Phase 1 only: Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention.
Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection.
Women who are pregnant or breastfeeding.
Previous vaccination with any coronavirus vaccine.
Individuals who receive treatment with immunosuppressive therapy, including cytotoxic agents or systemic corticosteroids, eg, for cancer or an autoimmune disease, or planned receipt throughout the study.
Phase 1 only: Regular receipt of inhaled/nebulized corticosteroids.
Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study.
Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation.
Previous participation in other studies involving study intervention containing lipid nanoparticles.
Phase 1 only: Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit.
Phase 1 only: Any screening hematology and/or blood chemistry laboratory value that meets the definition of a ≥ Grade 1 abnormality.
Phase 1 only: Positive test for HIV, hepatitis B surface antigen (HBsAg), hepatitis B core antibodies (HBc Abs), or hepatitis C virus antibodies (HCV Abs) at the screening visit.
Phase 1 only: SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention.
Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members.
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): NCT04368728

Locations
Show Show 155 study locations
Sponsors and Collaborators
BioNTech SE
Pfizer
Investigators
Study Director: Pfizer CT.gov Call Center Pfizer
More Information
Go to sections
Additional Information:
To obtain contact information for a study center near you, click here. This link exits the ClinicalTrials.gov site

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):
Vogel AB, Kanevsky I, Che Y, Swanson KA, Muik A, Vormehr M, Kranz LM, Walzer KC, Hein S, Güler A, Loschko J, Maddur MS, Ota-Setlik A, Tompkins K, Cole J, Lui BG, Ziegenhals T, Plaschke A, Eisel D, Dany SC, Fesser S, Erbar S, Bates F, Schneider D, Jesionek B, Sänger B, Wallisch AK, Feuchter Y, Junginger H, Krumm SA, Heinen AP, Adams-Quack P, Schlereth J, Schille S, Kröner C, de la Caridad Güimil Garcia R, Hiller T, Fischer L, Sellers RS, Choudhary S, Gonzalez O, Vascotto F, Gutman MR, Fontenot JA, Hall-Ursone S, Brasky K, Griffor MC, Han S, Su AAH, Lees JA, Nedoma NL, Mashalidis EH, Sahasrabudhe PV, Tan CY, Pavliakova D, Singh G, Fontes-Garfias C, Pride M, Scully IL, Ciolino T, Obregon J, Gazi M, Carrion R Jr, Alfson KJ, Kalina WV, Kaushal D, Shi PY, Klamp T, Rosenbaum C, Kuhn AN, Türeci Ö, Dormitzer PR, Jansen KU, Sahin U. BNT162b vaccines protect rhesus macaques from SARS-CoV-2. Nature. 2021 Feb 1. doi: 10.1038/s41586-021-03275-y. [Epub ahead of print]
Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, Perez JL, Pérez Marc G, Moreira ED, Zerbini C, Bailey R, Swanson KA, Roychoudhury S, Koury K, Li P, Kalina WV, Cooper D, Frenck RW Jr, Hammitt LL, Türeci Ö, Nell H, Schaefer A, Ünal S, Tresnan DB, Mather S, Dormitzer PR, Şahin U, Jansen KU, Gruber WC; C4591001 Clinical Trial Group. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020 Dec 31;383(27):2603-2615. doi: 10.1056/NEJMoa2034577. Epub 2020 Dec 10.
Walsh EE, Frenck RW Jr, Falsey AR, Kitchin N, Absalon J, Gurtman A, Lockhart S, Neuzil K, Mulligan MJ, Bailey R, Swanson KA, Li P, Koury K, Kalina W, Cooper D, Fontes-Garfias C, Shi PY, Türeci Ö, Tompkins KR, Lyke KE, Raabe V, Dormitzer PR, Jansen KU, Şahin U, Gruber WC. Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates. N Engl J Med. 2020 Dec 17;383(25):2439-2450. doi: 10.1056/NEJMoa2027906. Epub 2020 Oct 14.
Mulligan MJ, Lyke KE, Kitchin N, Absalon J, Gurtman A, Lockhart S, Neuzil K, Raabe V, Bailey R, Swanson KA, Li P, Koury K, Kalina W, Cooper D, Fontes-Garfias C, Shi PY, Türeci Ö, Tompkins KR, Walsh EE, Frenck R, Falsey AR, Dormitzer PR, Gruber WC, Şahin U, Jansen KU. Phase I/II study of COVID-19 RNA vaccine BNT162b1 in adults. Nature. 2020

Oct;586(7830):589-593. doi: 10.1038/s41586-020-2639-4. Epub 2020 Aug 12. Erratum in: Nature. 2021 Feb;590(7844):E26.

Responsible Party:
BioNTech SE
ClinicalTrials.gov Identifier:
NCT04368728 History of Changes
Other Study ID Numbers:
C4591001
2020-002641-42 (EudraCT Number)
First Posted:
April 30, 2020 Key Record Dates
Last Update Posted:
February 10, 2021
Last Verified:
February 2021
Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD:
Yes
Plan Description:
Pfizer will provide access to individual de-identified participant data and related study documents (e.g. protocol, Statistical Analysis Plan (SAP), Clinical Study Report (CSR)) upon request from qualified researchers, and subject to certain criteria, conditions, and exceptions. Further details on Pfizer's data sharing criteria and process for requesting access can be found at: https://www.pfizer.com/science/clinical_trials/trial_data_and_results/data_requests.
URL:
https://www.pfizer.com/science/clinical_trials/trial_data_and_results/data_requests

Studies a U.S. FDA-regulated Drug Product:
Yes
Studies a U.S. FDA-regulated Device Product:
No
Keywords provided by BioNTech SE:
COVID-19
Coronavirus
Vaccine
SARS-CoV-2
RNA Vaccine

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 : February 25, 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

Go to sections

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

Go to sections

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

Go to sections

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

Placebo Comparator: Placebo
Part A only: Participants will receive 1 IM injection of mRNA-1273-matching placebo on Day 1 and on Day 29, if the participant chooses.
Biological: Placebo
0.9% sodium chloride (normal saline) injection

Outcome Measures
Go to sections

Primary Outcome Measures :
Efficacy: Number of Participants with a First Occurrence of COVID-19 Starting 14 Days after Second Dose of mRNA-1273 [Time Frame: Part A only: Day 43 (14 days after second dose) up to Day 759 (2 years after second dose)]
Safety: Number of Participants with Adverse Events (AEs) or Medically Attended AEs (MAAEs) Leading to Withdrawal [Time Frame: Up to Day 759 (2 years after second dose)]
Safety: Number of Participants with Solicited Local and Systemic Adverse Reactions (ARs) [Time Frame: Part A only: Up to Day 8 (7 days after first dose) and up to Day 36 (7 days after second dose)]
Safety: Number of Participants with Unsolicited AEs [Time Frame: Up to Day 57 (28 days after each dose)]
Safety: Number of Participants with Serious AEs (SAEs) [Time Frame: Up to Day 759 (2 years after second dose)]

Secondary Outcome Measures :
Number of Participants with a First Occurrence of Severe COVID-19 Starting 14 Days after Second Dose of mRNA-1273 or Placebo [Time Frame: Day 43 (14 days after second dose) up to Day 759 (2 years after second dose)]
Clinical signs indicative of severe COVID-19 as predefined for the study.

Number of Participants with a First Occurrence of Either COVID-19 or SARS-CoV-2 Infection regardless of symptomatology or Severity Starting 14 Days after Second Dose of mRNA-1273 or Placebo [Time Frame: Day 43 (14 days after second dose) up to Day 759 (2 years after second dose)]
Clinical signs indicative of COVID-19 and SARS-CoV-2 Infection as predefined for the study.

Number of Participants with a Secondary Case Definition of COVID-19 Starting 14 days after Second Dose of mRNA-1273 or Placebo [Time Frame: Day 43 (14 days after second dose) up to Day 759 (2 years after second dose)]
Clinical signs indicative of secondary case definition of COVID-19 as predefined for the study.

Number of Participants with a First Occurrence of COVID-19 Starting 14 days after First Dose of mRNA-1273 or Placebo [Time Frame: Day 43 (14 days after first dose of the Blinded Phase) up to Day 759 (2 years after second dose)]
Clinical signs indicative of COVID-19 as predefined for the study.

Number of Participants with a First Occurrence of COVID-19 Starting 14 days after Second Dose of mRNA-1273 or Placebo Regardless of Evidence of Prior SARS-CoV-2 Infection [Time Frame: Day 43 (14 days after second dose) up to Day 759 (2 years after second dose)]
Clinical signs indicative of COVID-19 and SARS-CoV-2 infection as predefined for the study.

Number of Participants with a First Occurrence of SARS-CoV-2 Infection in the Absence of Symptoms Defining COVID-19 Starting 14 days after Second Dose of mRNA-1273 or Placebo [Time Frame: Day 43 (14 days after second dose) up to Day 759 (2 years after second dose)]
Clinical signs indicative of COVID-19 and SARS-CoV-2 infection as predefined for the study.

Geometric Mean Titer (GMT) of SARS-CoV-2 Specific Neutralizing Antibody (nAb) [Time Frame: Day 1, Day 29, Day 57, Day 209, Day 394, and Day 759]
Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Specific nAb [Time Frame: Day 1, Day 29, Day 57, Day 209, Day 394, and Day 759]
Quantified Levels or GMT of S Protein-Specific Binding Antibody (bAb) [Time Frame: Day 1, Day 29, Day 57, Day 209, Day 394, and Day 759]
GMFR of S Protein Specific bAb [Time Frame: Day 1, Day 29, Day 57, Day 209, Day 394, and Day 759]

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:

Participants who are at high risk of SARS-CoV-2 infection, defined as adults whose locations or circumstances put them at appreciable risk of exposure to SARS-CoV-2 and COVID-19.
Understands and agrees to comply with the study procedures and provides written informed consent.
Able to comply with study procedures based on the assessment of the Investigator.
Female participants of non-childbearing potential may be enrolled in the study. Non-childbearing 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 without an alternative medical cause). A follicle-stimulating hormone (FSH) level may be measured at the discretion of the Investigator to confirm postmenopausal status.
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 and on the day of the first dose (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 dose (Day 1).
Has agreed to continue adequate contraception through 3 months following the second dose on Day 29.
Is not currently breastfeeding.
Healthy adults or adults with pre-existing medical conditions who are in stable condition. A stable medical condition is defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment.
Additional Inclusion Criteria for Part B:
Participants who were previously enrolled in the mRNA-1273-P301 study and chose to be unblinded.
Exclusion Criteria:
Is acutely ill or febrile 72 hours prior to or at Screening. Fever is defined as a body temperature ≥38.0°Celsius/100.4°Fahrenheit. 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.
Is pregnant or breastfeeding.
(Part A Only) Known history of SARS-CoV-2 infection.
Prior administration of an investigational coronavirus (SARS-CoV, Middle East Respiratory Syndrome [MERS]-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19.
(Part A Only) Demonstrated inability to comply with the study procedures.
(Part A Only) An immediate family member or household member of this study's personnel.
Known or suspected allergy or history of anaphylaxis, urticaria, or other significant adverse reaction to the vaccine or its excipients.
Bleeding disorder considered a contraindication to intramuscular injection or phlebotomy.
Has received or plans to receive a vaccine within 28 days prior to the first dose (Day 1) or plans to receive a non-study vaccine within 28 days prior to or after any dose of investigational product (except for seasonal influenza vaccine).
Has participated in an interventional clinical study within 28 days prior to the day of enrollment.

Immunosuppressive or immunodeficient state, including human immunodeficiency virus (HIV) infection, asplenia, and recurrent severe infections.
Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥20 milligram (mg)/day of prednisone equivalent).
Has received systemic immunoglobulins or blood products within 3 months prior to the day of Screening.
Has donated ≥450 milliliters (mL) of blood products within 28 days prior to Screening.
Contacts and Locations
Go to sections

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): NCT04470427

Locations
Show Show 100 study locations
Sponsors and Collaborators
ModernaTX, Inc.
Biomedical Advanced Research and Development Authority
National Institute of Allergy and Infectious Diseases (NIAID)
More Information
Go to sections
Additional Information:
Click here to access the website, www.modernatx.com/cove-study, for additional information for the study, such as Study Overview, Participation, and Site Locations, along with contact numbers for each location for the study. This link exits the ClinicalTrials.gov site

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):
Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, Diemert D, Spector SA, Rouphael N, Creech CB, McGettigan J, Khetan S, Segall N, Solis J, Brosz A, Fierro C, Schwartz H, Neuzil K, Corey L, Gilbert P, Janes H, Follmann D, Marovich M, Mascola J, Polakowski L, Ledgerwood J, Graham BS, Bennett H, Pajon R, Knightly C, Leav B, Deng W, Zhou H, Han S, Ivarsson M, Miller J, Zaks T; COVE Study Group. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. N Engl J Med. 2021 Feb 4;384(5):403-416. doi: 10.1056/NEJMoa2035389. Epub 2020 Dec 30.

Responsible Party:
ModernaTX, Inc.
ClinicalTrials.gov Identifier:
NCT04470427 History of Changes

Other Study ID Numbers:
mRNA-1273-P301
75A50120C00034 (Other Grant/Funding Number: BARDA)
First Posted:
July 14, 2020 Key Record Dates
Last Update Posted:
February 25, 2021
Last Verified:
February 2021
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

A Study of Ad26.COV2.S for the Prevention of SARS-CoV-2-Mediated COVID-19 in Adult Participants (ENSEMBLE)

ClinicalTrials.gov Identifier: NCT04505722

Recruitment Status : Active, not recruiting
First Posted : August 10, 2020
Last Update Posted : February 9, 2021
Sponsor:
Janssen Vaccines & Prevention B.V.
Information provided by (Responsible Party):
Janssen Vaccines & Prevention B.V.

Study Details Tabular ViewNo Results PostedDisclaimerHow to Read a Study Record
Study Description
Go to sections
Brief Summary:
The study will enroll approximately 40,000 participants in order to evaluate the efficacy of Ad26.COV2.S in the prevention of molecularly confirmed moderate to severe/critical COVID-19, as compared to placebo, in adult participants.

Condition or disease Intervention/treatment Phase
Participants With or Without Stable Co-morbidities Associated With Progression to Severe COVID-19 at Different Stages of the Protocol
Biological: Ad26.COV2.S
Other: Placebo
Phase 3

Study Design
Go to sections
Study Type :
Interventional (Clinical Trial)
Actual Enrollment :
44325 participants
Allocation:
Randomized
Intervention Model:
Parallel Assignment
Masking:
Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose:
Prevention
Official Title:
A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older
Actual Study Start Date :
September 7, 2020
Actual Primary Completion Date :

January 22, 2021
Estimated Study Completion Date :
January 2, 2023
Arms and Interventions
Go to sections
Arm Intervention/treatment
Experimental: Ad26.COV2.S
Participants will receive intramuscular (IM) injection of Ad26.COV2.S at a dose level of 5*10^10 virus particles (vp) as single dose vaccine on Day 1.
Biological: Ad26.COV2.S
Ad26.COV2.S will be administered at a dose level of 5*10^10 virus particles (vp) as single dose vaccine on Day 1.
Other Names:
JNJ-78436735
Ad26COVS1

Placebo Comparator: Placebo
Participants will receive IM injection of placebo on Day 1.
Other: Placebo
Participants will receive Placebo.

Outcome Measures
Go to sections

Primary Outcome Measures :
Number of Participants with First Occurrence of Molecularly Confirmed Moderate to Severe/Critical Coronavirus Disease (COVID-19) with Seronegative Status [Time Frame: 14 Days post-vaccination (Day 15) to end of study (2 years and 1 month)]
Moderate defined as one sign or symptom from a list of signs and symptoms, such as respiratory rate greater than or equal to (>=) 20 breaths per minute and symptoms such as shortness of breath or two signs or symptoms from a list of sign and symptoms or severe COVID-19 defined in FDA guidance.

Number of Participants with First Occurrence of Molecularly Confirmed Moderate to Severe/Critical Coronavirus Disease (COVID-19) with Seronegative Status [Time Frame: 28 Days post-vaccination (Day 29) to end of study (2 years and 1 month)]
Moderate defined as one sign or symptom from a list of signs and symptoms, such as respiratory rate greater than or equal to (>=) 20 breaths per minute and symptoms such as shortness of breath or two signs or symptoms from a list of sign and symptoms or severe COVID-19 defined in FDA guidance.

Secondary Outcome Measures :

Number of Participants with First Occurrence of Molecularly Confirmed Severe/Critical Coronavirus Disease (COVID-19) with Seronegative Status [Time Frame: 14 Days post-vaccination (Day 15) to end of study (2 years and 1 month)]
Severe defined as one sign or symptom from a list of signs and symptoms, such as respiratory rate greater than or equal to (>=) 30 breaths per minute and symptoms such as shortness of breath or two signs or symptoms from a list of sign and symptoms or severe COVID-19 defined in FDA guidance.

Number of Participants with First Occurrence of Molecularly Confirmed Severe/Critical Coronavirus Disease (COVID-19) with Seronegative Status [Time Frame: 28 Days post-vaccination (Day 29) to end of study (2 years and 1 month)]
Severe defined as one sign or symptom from a list of signs and symptoms, such as respiratory rate greater than or equal to (>=) 30 breaths per minute and symptoms such as shortness of breath or two signs or symptoms from a list of sign and symptoms or severe COVID-19 defined in FDA guidance.

Number of Participants with First Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 Regardless of their Serostatus [Time Frame: 1 Day post-vaccination (Day 2) to end of study (2 years and 1 months)]
Moderate defined as one sign or symptom from a list of signs and symptoms, such as respiratory rate >= 20 breaths per minute and symptoms such as shortness of breath or two signs or symptoms from a list of sign and symptoms or severe COVID-19 defined in FDA guidance.

Number of Participants with First Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 Regardless of their Serostatus [Time Frame: 14 days post-vaccination (Day 15) up to end of study (2 years and 1 month)]
Moderate defined as one sign or symptom from a list of signs and symptoms, such as respiratory rate >= 20 breaths per minute and symptoms such as shortness of breath or two signs or symptoms from a list of sign and symptoms or severe COVID-19 defined in FDA guidance.

Number of Participants with First Occurrence of Molecularly Confirmed Moderate to Severe/Critical COVID-19 Regardless of Their Serostatus [Time Frame: 28 days post-vaccination (Day 15) up to end of study (2 years and 1 month)]
Moderate defined as one sign or symptom from a list of signs and symptoms, such as respiratory rate greater than or equal to (>=) 20 breaths per minute and symptoms such as shortness of breath or two signs or symptoms from a list of sign and symptoms or severe COVID-19 defined in FDA guidance.

Number of Participants with First Occurrence of COVID-19 Requiring Medical Intervention [Time Frame: 14 days post-vaccination (Day 15) up to end of study (2 years and 1 month)]

Number of participants with first occurrence of COVID-19 requiring medical intervention (such as a composite endpoint of hospitalization, intensive care unit (ICU) admission, mechanical ventilation, and extracorporeal membrane oxygenation (ECMO), linked to objective measures such as decreased oxygenation, X-ray or CT findings) or linked to any molecularly confirmed, COVID-19 at least 14 days post vaccination will be reported.

Number of Participants with First Occurrence of COVID-19 Requiring Medical Intervention [Time Frame: 28 Days post-vaccination (Day 29) to end of study (2 years and 1 month)]
Number of participants with first occurrence of COVID-19 requiring medical intervention (such as a composite endpoint of hospitalization, intensive care unit (ICU) admission, mechanical ventilation, and extracorporeal membrane oxygenation (ECMO), linked to objective measures such as decreased oxygenation, X-ray or CT findings) or linked to any molecularly confirmed, COVID-19 at least 28 days post vaccination will be reported.

SARS-CoV-2 Viral Load as Assessed by Quantitative Reverse-Transcriptase Polymerase Chain Reaction (RT-PCR) in Participants with Molecularly Confirmed, Moderate to Severe/Critical COVID-19 [Time Frame: 14 Days post-vaccination (Day 15) to end of study (2 years and 1 month)]
The viral load of SARS-CoV-2 will be assessed in confirmed COVID-19 cases using RT-PCR. Nasal swabs will be used to detect and/or quantify SARS-CoV-2.

Number of Participants with First Occurrence of Molecularly Confirmed Mild COVID-19 [Time Frame: 14 Days post-vaccination (Day 15) to end of study (2 years and 1 month)]
Molecularly confirmed mild COVID-19 is defined as a SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (example, nasal swab sample, sputum sample, throat swab sample, saliva sample) or other sample. Mild COVID-19 includes: Fever, sore throat, malaise, headache, muscle pain, gastrointestinal symptoms, cough, chest congestion, runny nose, wheezing, skin rash, eye irritation or discharge, or chills, without shortness of breath or dyspnea.

Number of Participants with First Occurrence of Molecularly Confirmed Mild COVID-19 [Time Frame: 28 Days post-vaccination (Day 29) to end of study (2 years and 1 month)]
Molecularly confirmed mild COVID-19 is defined as a SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (example, nasal swab sample, sputum sample, throat swab sample, saliva sample) or other sample. Mild COVID-19 includes: Fever, sore throat, malaise, headache, muscle pain, gastrointestinal symptoms, cough, chest congestion, runny nose, wheezing, skin rash, eye irritation or discharge, or chills, without shortness of breath or dyspnea.

Number of Participants with First Occurrence of Molecularly Confirmed COVID-19 Defined by the US Food and Drug Administration (FDA) Harmonized case Definition [Time Frame: 14 Days post-vaccination (Day 15) to end of study (2 years and 1 month)]
Molecularly confirmed moderate and severe/critical COVID-19 defined as a positive SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract

sample (example, nasal swab sample, sputum sample, throat swab sample, saliva sample) or other sample; and COVID-19 symptoms consistent with those defined by the US FDA harmonized case Definition at the time of finalization of this protocol: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea.

Number of Participants with First Occurrence of Molecularly Confirmed COVID-19 Defined by the US Food and Drug Administration (FDA) Harmonized case Definition [Time Frame: 28 Days post-vaccination (Day 29) to end of study (2 years and 1 month)]
Molecularly confirmed moderate and severe/critical COVID-19 defined as a positive SARS-CoV-2 positive RT-PCR or molecular test result from any available respiratory tract sample (example, nasal swab sample, sputum sample, throat swab sample, saliva sample) or other sample; and COVID-19 symptoms consistent with those defined by the US FDA harmonized case Definition at the time of finalization of this protocol: fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea.

Burden of Disease (BOD) Based on First Occurrence of Molecularly Confirmed Symptomatic COVID-19 [Time Frame: 14 Days post-vaccination (Day 15) to end of study (2 years and 1 month)]
BOD will be evaluated based on the first occurrence of molecularly confirmed COVID-19, including mild, moderate or severe/critical COVID-19 case.

BOD Based on First Occurrence of Molecularly Confirmed Symptomatic COVID-19 [Time Frame: 28 Days post-vaccination (Day 29) to end of study (2 years and 1 month)]
BOD will be evaluated based on the first occurrence of molecularly confirmed COVID-19, including mild, moderate or severe/critical COVID-19 case.

Serologic Conversion Between Baseline and (Day 1; Pre-vaccination), Day 71, 6 Months and 1-Year Post-vaccination using an Enzyme-linked Immunosorbent Assay (ELISA) [Time Frame: Between baseline (Day 1; pre-vaccination) and Day 71, 6 Months, 1-Year post-vaccination (up to 52 Weeks)]
Serologic conversion between baseline and (Day 1; pre-vaccination), Day 71, 6 Months, 1 year post-vaccination using an ELISA and/or SARS-CoV- 2 immunoglobulin assay that is dependent on the SARS-CoV-2 nucleocapsid (N) protein will be reported.

Number of Participants with First Occurrence of SARS-CoV-2 Infection (Serologically and/or Molecularly Confirmed) [Time Frame: 28 Days post-vaccination (Day 29) to end of study (2 years and 1 month)]
Number of participants with first occurrence of SARS-CoV-2 infection (serologically and/or molecularly confirmed) with onset at least 28 days after vaccination (Day 29) to end of Study (2 years and 1 month) will be reported.

Number of Participants with Serious Adverse Events (SAEs) [Time Frame: Up to 104 Weeks]

SAE is any untoward medical occurrence that at any dose may result in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a suspected transmission of any infectious agent via a medicinal product.

Number of Participants with Medically-Attended Adverse Events (MAAEs) [Time Frame: Up to 6 Months]
MAAEs are defined as AEs with medically-attended visits including hospital, emergency room, urgent care clinic, or other visits to or from medical personnel for any reason.

Number of Participants with Medically-Attended Adverse Events (MAAEs) Leading to Study Discontinuation [Time Frame: Up to 104 Weeks]
MAAEs are defined as AEs with medically-attended visits including hospital, emergency room, urgent care clinic, or other visits to or from medical personnel for any reason. Routine study visits will not be considered medically-attended visits. New onset of chronic diseases will be collected as part of the MAAEs.

Number of Participants with Solicited Local Adverse Events (AEs) During 7 Days Following Vaccination [Time Frame: Up to Day 8 (7 Days after first vaccination on Day 1)]
Participants who will be enrolled in safety subset will be asked to note in the e-Diary occurrences of injection site pain/tenderness, erythema, and swelling at the study vaccine injection site daily for 7 days post-vaccination (day of vaccination and the subsequent 7 days).

Number of Participants with Solicited Systemic AEs During 7 Days Following Vaccination [Time Frame: Up to Day 8 (7 Days after first vaccination on Day 1)]
Participants who will be enrolled in safety subset will be instructed on how to record daily temperature using a thermometer provided for home use. Participants should record the temperature in the e-Diary in the evening of the day of vaccination, and then daily for the next 7 days approximately at the same time each day. If more than 1 measurement is made on any given day, the highest temperature of that day will be recorded in the e-Diary. Fever is defined as endogenous elevation of body temperature >= 38.0 degree Celsius or >=100.4-degree Fahrenheit, as recorded in at least 1 measurement. Participants will also be instructed on how to note signs and symptoms in the e-Diary on a daily basis for 7 days post-vaccination (day of vaccination and the subsequent 7 days), for the following events: fatigue, headache, nausea, myalgia.

Number of Participants with Unsolicited Local Adverse Events (AEs) During 28 Days Post-vaccination [Time Frame: Up to Day 29 (28 Days after first vaccination on Day 1)]
Unsolicited AEs are all AEs for which the participant is not specifically questioned in the participant diary.

SARS-CoV-2 Neutralizing Antibody Titers as Assessed by Virus Neutralization Assay (VNA) [Time Frame: Up to 104 Weeks]

Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) neutralizing antibody titers as assessed by VNA to measure the humoral immune responses will be reported

SARS-CoV-2 Binding Antibodies Assessed by ELISA [Time Frame: Up to 104 Weeks]
SARS-CoV-2 binding antibodies as assessed by enzyme-linked immunosorbent assay (ELISA) to measure humoral immune response will be reported.

Eligibility Criteria
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Ages Eligible for Study:
18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:
All
Accepts Healthy Volunteers:
Yes
Criteria
Inclusion Criteria:
Contraceptive (birth control) use should be consistent with local regulations regarding the acceptable methods of contraception for those participating in clinical studies
All participants of childbearing potential must: have a negative highly sensitive urine pregnancy test at screening; and have a negative highly sensitive urine pregnancy test immediately prior to each study vaccine administration
Participant agrees to not donate bone marrow, blood, and blood products from the first study vaccine administration until 3 months after receiving the last dose of study vaccine
Must be willing to provide verifiable identification, has means to be contacted and to contact the investigator during the study
Must be able to read, understand, and complete questionnaires in the electronic clinical outcome assessment (eCOA) (that is, the coronavirus disease-2019 [COVID 19] signs and symptoms surveillance question, the e-Diary, and the electronic patient-reported outcomes (ePROs). Note: Participants with visual impairment are eligible for study participation and may have caregiver assistance in completing the electronic clinical outcome assessment (eCOA) questionnaires
Exclusion Criteria:
Participant has a clinically significant acute illness (this does not include minor illnesses such as diarrhea or mild upper respiratory tract infection) or temperature greater than or equal to (>=)

38.0 degree Celsius (100.4-degree Fahrenheit) within 24 hours prior to the planned first dose of study vaccine; randomization at a later date is permitted at the discretion of the investigator and after consultation with the sponsor
Participant received or plans to receive: (a) licensed live attenuated vaccines - within 28 days before or after planned administration of study vaccine ; and (b) other licensed (not live) vaccines - within 14 days before or after planned administration of study vaccine
Participant previously received a coronavirus vaccine
Participant received an investigational drug (including investigational drugs for prophylaxis of COVID-19) within 30 days or used an invasive investigational medical device within 30 days or received investigational immunoglobulin or monoclonal antibodies within 3 months, or received convalescent serum for COVID-19 treatment within 4 months or received an investigational vaccine (including investigational Adenoviral-vectored vaccines) within 6 months before the planned administration of the first dose of study vaccine or is currently enrolled or plans to participate in another investigational study during the course of this study
Contacts and Locations
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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT04505722

Locations
Show Show 213 study locations
Sponsors and Collaborators
Janssen Vaccines & Prevention B.V.
Investigators
Study Director: Janssen Vaccines & Prevention B.V. Clinical Trial Janssen Vaccines & Prevention B.V.
More Information
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Additional Information:
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Responsible Party:
Janssen Vaccines & Prevention B.V.
ClinicalTrials.gov Identifier:
NCT04505722 History of Changes
Other Study ID Numbers:
CR108876
VAC31518COV3001 (Other Identifier: Janssen Vaccines & Prevention B.V.)

First Posted:
August 10, 2020 Key Record Dates
Last Update Posted:
February 9, 2021
Last Verified:
February 2021
Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD:
Yes
Plan Description:
The data sharing policy of the Janssen Pharmaceutical Companies of Johnson & Johnson is available at www.janssen.com/clinical-trials/transparency. As noted on this site, requests for access to the study data can be submitted through Yale Open Data Access (YODA) Project site at yoda.yale.edu
URL:
https://www.janssen.com/clinical-trials/transparency

Studies a U.S. FDA-regulated Drug Product:
Yes
Studies a U.S. FDA-regulated Device Product:
No
Keywords provided by Janssen Vaccines & Prevention B.V.:
Prevention
Vaccine
Additional relevant MeSH terms:
Disease Progression
Disease Attributes
Pathologic Processes