COVID-19 Information
Public health information (CDC) | Research information (NIH) | SARS-CoV-2 data (NCBI) | Prevention and treatment information (HHS) | Español

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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. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT04368728

Recruitment Status : Recruiting
First Posted : April 30, 2020
Last Update Posted : December 17, 2021
See Contacts and Locations

Sponsor:
BioNTech SE

Collaborator:
Pfizer

Information provided by (Responsible Party):
BioNTech SE

Study Description

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 3 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;
- As a booster;
- 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 efficacy evaluation in Phase 2/3 is BNT162b2 at a dose of 30 µg.

Participants who originally received placebo will be offered the opportunity to receive BNT162b2 at defined points as part of the study.

In order to describe the boostability of BNT162, and potential heterologous protection against emerging SARS-CoV-2 VOCs, an additional dose of BNT162b2 at 30 µg will be given to Phase 1 participants approximately 6 to 12 months after their second dose of BNT162b1 or BNT162b2. This will provide an early assessment of the safety of a third dose of BNT162, as well as its immunogenicity.

The assessment of boostability will be further expanded in a subset of Phase 3 participants at selected sites in the US who will receive a third dose of BNT162b2 at 30 µg or a third and potentially a fourth dose of prototype BNT162b2VOC at 30 µg (BNT162b2s01, based upon the South African variant and hereafter referred to as BNT162b2SA). A further subset of Phase 3 participants will receive a third, lower, dose of BNT162b2 at 5 or 10 µg.

To further describe potential homologous and heterologous protection against emerging SARS-CoV-2 VOCs, a new cohort of participants will be enrolled who are COVID-19 vaccine-naïve (ie, BNT162b2-naïve) and have not experienced COVID-19. They will receive BNT162b2SA given as a 2-dose series, separated by 21 days.

To reflect current and anticipated recommendations for COVID 19 vaccine boosters, participants in C4591001 who meet specified recommendations and have not already received one, will be offered a third dose of BNT162b2 after their second dose of BNT162.

Condition or disease	Intervention/treatment	Phase
SARS-CoV-2 Infection COVID-19	Biological: BNT162b1 Biological: BNT162b2 Other: Placebo Biological: BNT162b2SA	Phase 2 Phase 3

Study Design

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 : May 15, 2023
Estimated Study Completion Date : May 15, 2023

Arms and Interventions

Arm	Intervention/treatment
Experimental: 10 µg dose, 18-55 years of age (2 doses)	Biological: BNT162b1 Intramuscular injection Biological: BNT162b2 Intramuscular injection
Experimental: 20 µg dose, 18-55 years of age (2 doses)	Biological: BNT162b1 Intramuscular injection Biological: BNT162b2 Intramuscular injection
Experimental: 30 µg dose, 18-55 years of age (2 doses)	Biological: BNT162b1 Intramuscular injection Biological: BNT162b2 Intramuscular injection
Experimental: 10 µg dose, 65-85 years of age (2 doses)	Biological: BNT162b1 Intramuscular injection Biological: BNT162b2 Intramuscular injection
Experimental: 20 µg dose, 65-85 years of age (2 doses)	Biological: BNT162b1 Intramuscular injection Biological: BNT162b2 Intramuscular injection
Experimental: 30 µg dose, 65-85 years of age (2 doses)	Biological: BNT162b1 Intramuscular injection Biological: BNT162b2 Intramuscular injection
Experimental: 30 µg 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: 100 µg 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
Experimental: Booster vaccination of Phase 1 participants with BNT162b2 at a dose of 30 µg	Biological: BNT162b2 Intramuscular injection
Experimental: Booster vaccination of Phase 3 participants with BNT162b2 at a dose of 30 µg	Biological: BNT162b2 Intramuscular injection
Experimental: Booster vaccination of Phase 3 participants with BNT162b2SA at a dose of 30 µg	Biological: BNT162b2SA Intramuscular injection
Experimental: Vaccination of BNT162b2-naive participants with BNT162b2SA at a dose of 30 µg	Biological: BNT162b2SA Intramuscular injection
Experimental: Booster and further vaccination of Phase 3 participants with BNT162b2SA at a dose of 30 µg	Biological: BNT162b2SA Intramuscular injection
Experimental: Booster vaccination of Phase 3 participants with BNT162b2 at a dose of 5 µg	Biological: BNT162b2 Intramuscular injection
Experimental: Booster vaccination of Phase 3 participants with BNT162b2 at a dose of 10 µg	Biological: BNT162b2 Intramuscular injection

Outcome Measures

Primary Outcome Measures :

1. 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.
2. 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.
3. 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
4. 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
5. 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
6. 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
7. 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
8. 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
9. 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
10. 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
11. 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.
12. 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.
13. 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
14. 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
15. 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.
16. 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.
17. 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
18. 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
19. 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
20. 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
21. 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
22. 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
23. 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.
24. 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.
25. In participants who receive BNT162b2SA given as 1 or 2 doses, percentage of participants reporting adverse events [Time Frame: From dose 1 through 1 month after the last dose]
   As elicited by investigational site staff
26. In participants who receive BNT162b2SA given as 1 or 2 doses, percentage of participants reporting serious adverse events [Time Frame: From dose 1 through 5 or 6 months after the last dose]
   As elicited by investigational site staff
27. In participants, who receive BNT162b2SA given as 1 or 2 doses, 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.
28. In participants who receive BNT162b2SA given as 1 or 2 doses, 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.
29. In participants who receive a third dose of BNT162b2 as part of the subset for evaluation of boostability and protection against emerging VOCs, percentage of participants reporting adverse events [Time Frame: From the third dose through 1 month after the third dose]
   As elicited by investigational site staff
30. In participants who receive a third dose of BNT162b2 as part of the subset for evaluation of boostability and protection against emerging VOCs, percentage of participants reporting serious adverse events [Time Frame: From the third dose through 6 months after the third dose]
   As elicited by investigational site staff
31. In participants who receive a third dose of BNT162b2 as part of the subset for evaluation of boostability and protection against emerging VOCs, percentage of participants reporting local reactions [Time Frame: For 7 days after the third dose]
   Pain at the injection site, redness, and swelling as self-reported on electronic diaries.
32. In participants who receive a third dose of BNT162b2 as part of the subset for evaluation of boostability and protection against emerging VOCs, percentage of participants reporting systemic events [Time Frame: For 7 days after the third dose]
   Fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain as self-reported on electronic diaries.
33. In participants who receive a third dose of BNT162b2 as a result of current or anticipated recommendations, percentage of participants reporting adverse events [Time Frame: From the third dose through 1 month after the third dose]
   As elicited by investigational site staff
34. In participants who receive a third dose of BNT162b2 as a result of current or anticipated recommendations, percentage of participants reporting serious adverse events [Time Frame: From the third dose through 6 months after the third dose]
   As elicited by investigational site staff
35. Noninferiority of the SARS-CoV-2 reference strain neutralizing titers after a third dose of BNT162b2 at 30 µg compared to after 2 doses of BNT162b2, in the same individuals [Time Frame: 1 month after the third dose]
   As measured at the central laboratory
36. Noninferiority of the SARS-CoV-2 SA strain neutralizing titers after one dose of BNT162b2SA compared to the SARS-CoV-2 reference strain neutralizing titers after 2 doses of BNT162b2, in the same individuals [Time Frame: 1 month after the third dose]
   As measured at the central laboratory
37. Noninferiority of the SARS-CoV-2 SA strain neutralizing titers after 2 doses of BNT162b2SA compared to the SARS-CoV-2 reference strain neutralizing titers after 2 doses of BNT162b2 [Time Frame: 1 month after the second dose]
   As measured at the central laboratory

Secondary Outcome Measures :

1. 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
2. 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
3. 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
4. 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
5. 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
6. 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
7. 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
8. 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
9. 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
10. 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
11. 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
12. 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
13. 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
14. 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
15. 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
16. 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
17. 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
18. 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
19. 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
20. 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
21. Noninferiority of the SARS-CoV-2 SA strain neutralizing titers after a third dose of BNT162b2 at 30 µg compared to the SARS-CoV-2 reference strain neutralizing titers after 2 doses of BNT162b2, in the same individuals [Time Frame: 1 month after the third dose]
   As measured at the central laboratory
22. Noninferiority of the SARS-CoV-2 reference strain neutralizing titers after one dose of BNT162b2SA compared to after 2 doses of BNT162b2, in the same individuals [Time Frame: 1 month after the first dose of BNT162b2SA]
   As measured at the central laboratory
23. Comparison of the SARS-CoV-2 SA strain neutralizing titers after 1 dose of BNT162b2SA to after a third dose of BNT162b2 at 30 µg [Time Frame: 1 month after the first dose of BNT162b2SA/third dose of BNT162b2]
   As measured at the central laboratory
24. Comparison of the SARS-CoV-2 SA strain neutralizing titers after 2 doses of BNT162b2SA to the SARS-CoV-2 reference strain neutralizing titers after 2 doses of BNT162b2, in the same individuals [Time Frame: 1 month after the second dose of BNT162b2SA]
   As measured at the central laboratory
25. Comparison of the SARS-CoV-2 SA strain neutralizing titers after 2 doses of BNT162b2SA to after 2 doses of BNT162b2 [Time Frame: 1 month after the second dose]
   As measured at the central laboratory
26. Comparison of the SARS-CoV-2 reference strain neutralizing titers after 2 doses of BNT162b2SA to after 2 doses of BNT162b2 [Time Frame: 1 month after the second dose]
   As measured at the central laboratory

Eligibility Criteria

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). For the boostability and protection-against-VOCs subset: Existing participants enrolled to receive a third dose of BNT162b2 at 30 µg or BNT162b2SA; male or female participants between the ages of 18 and 55 years, inclusive, at rerandomization.

Newly enrolled participants enrolled to receive 2 doses of BNT162b2SA; male or female participants between the ages of 18 and 55 years, inclusive, at enrollment.

Existing participants enrolled to receive a third dose of BNT162b2 at 5 or 10 µg; male or female participants ≥18 years at rerandomization.

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.
- Boostability and protection-against-VOCs existing participant subset only: Participants who provided a serum sample at Visit 3, with Visit 3 occurring within the protocol-specified window.
- 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 through and including 6 months after the last dose of study intervention, with the exception of non-Pfizer interventional studies for prevention of COVID 19, which are prohibited throughout 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

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***

Contacts
Contact: Pfizer CT.gov Call Center 1-800-718-1021 ClinicalTrials.gov_Inquiries@pfizer.com

Locations
Show 166 study locations

Sponsors and Collaborators
BioNTech SE
Pfizer

Investigators
Study Director: Pfizer CT.gov Call Center Pfizer

More Information

Additional Information:
To obtain contact information for a study center near you, click here.

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Thomas SJ, Moreira ED Jr, Kitchin N, Absalon J, Gurtman A, Lockhart S, Perez JL, Pérez Marc G, Polack FP, Zerbini C, Bailey R, Swanson KA, Xu X, Roychoudhury S, Koury K, Bouguermouh S, Kalina WV, Cooper D, Frenck RW Jr, Hammitt LL, Türeci Ö, Nell H, Schaefer A, Ünal S, Yang Q, Liberator P, Tresnan DB, Mather S, Dormitzer PR, Şahin U, Gruber WC, Jansen KU; C4591001 Clinical Trial Group. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months. N Engl J Med. 2021 Nov 4;385(19):1761-1773. doi: 10.1056/NEJMoa2110345. Epub 2021 Sep 15.

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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

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COVID-19
Coronavirus
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RNA Vaccine

Additional relevant MeSH terms:

COVID-19	Coronavirus Infections
Respiratory Tract Infections	Coronaviridae Infections
Infections	Nidovirales Infections
Pneumonia, Viral	RNA Virus Infections
Pneumonia	Lung Diseases
Virus Diseases	Respiratory Tract Diseases