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

ClinicalTrials.gov Identifier: NCT04368728

Recruitment Status : Recruiting
First Posted : April 30, 2020
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See **Contacts and Locations**

Sponsor:
BioNTech SE

Collaborator:

Pfizer

Information provided by (Responsible Party):

BioNTech SE

Study Description

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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.

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

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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 2, 2023
Estimated Study Completion Date :	May 2, 2023