

CT Study to Describe the Safety, To X Comment faire des captures d' X

https://clinicaltrials.gov/ct2/show/NCT04368728?cond=Covid19&intr=Vaccine& 90% capture d'ecran

### 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 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	Biological: BNT162b1	Phase 2
COVID-19	Biological: BNT162b2	Phase 3
	Other: Placebo	

### 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:** August 3, 2021

**Estimated Study Completion Date:** January 31, 2023

### Arms and Interventions

Arm	Intervention/treatment

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VACCINES=COBAYES

FIN DE LA PHASE 3 LE 31 JANVIER 2023  
Essais du « vaccin anti-covid 19 » Pfizer- BioNtech