Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California

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: NCT04848584

Recruitment Status : Active, not recruiting
First Posted : April 19, 2021
Last Update Posted : August 11, 2021

Sponsor:
Pfizer

Information provided by (Responsible Party):
Pfizer

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

Brief Summary:
The primary objective of this study is to determine the vaccine effectiveness of 2 doses of Pfizer-BioNTech BNT162b2 vaccine against COVID-19-associated hospitalization. There will be a large retrospective database study using two parallel study designs: a test-negative case-control design and a retrospective cohort design. Exploratory analyses of VE estimates by strain type will be conducted.

Condition or disease	Intervention/treatment
COVID-19	Biological: Primary Exposure Status of Pfizer-BioNTech COVID-19 Vaccine

Detailed Description:
The primary objective of this study is to determine the vaccine effectiveness (VE) of 2-doses of Pfizer's BNT162b2 vaccine against COVID-19-associated hospitalization. In addition, VE of 1 dose and at least one dose will be determined. Other outcomes in addition to hospitalization to be assessed include COVID-19-associated ED admissions, ICU admissions, outpatient visits and death. To assess VE, we propose a large retrospective database study using two parallel study designs: a test-negative case-control design and a retrospective cohort design. The test-negative design (TND) will assess VE against COVID-19 hospitalization (primary endpoint) and emergency department (ED) admission. The retrospective cohort analysis will assess VE against COVID-19 hospitalization (primary), ICU admission, death, ED admission, and outpatient disease (with no subsequent hospitalization within 14 days). We will further conduct exploratory analyses of VE estimates by strain type.

Study Design

Study Type :	Observational
Estimated Enrollment :	999 participants
Observational Model:	Case-Control
Time Perspective:	Retrospective
Official Title:	Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Per-manente Southern California
Actual Study Start Date :	May 15, 2021
Estimated Primary Completion Date :	April 1, 2022
Estimated Study Completion Date :	July 30, 2023

Groups and Cohorts

Group/Cohort	Intervention/treatment
Fully vaccinated 2 doses of BNT162b2 received with ≥7 days between receipt of the 2nd dose and the index date. This group will serve as the 'exposed' group evaluated in the primary objective.	Biological: Primary Exposure Status of Pfizer-BioNTech COVID-19 Vaccine Pfizer-BioNTech COVID-19 vaccine Other Name: COVID VACCINE
Partially vaccinated 1 dose (only) of BNT162b2 received with ≥14 days between receipt of the 1st dose and the index date.	Biological: Primary Exposure Status of Pfizer-BioNTech COVID-19 Vaccine Pfizer-BioNTech COVID-19 vaccine Other Name: COVID VACCINE
Ever vaccinated ≥1 dose of BNT162b2 received with ≥14 days between index date and receipt of the 1st dose	Biological: Primary Exposure Status of Pfizer-BioNTech COVID-19 Vaccine Pfizer-BioNTech COVID-19 vaccine Other Name: COVID VACCINE
Never vaccinated never received BNT162b2. This group will serve as the reference exposure group (i.e., 'unexposed' group) in all VE analyses	Biological: Primary Exposure Status of Pfizer-BioNTech COVID-19 Vaccine Pfizer-BioNTech COVID-19 vaccine Other Name: COVID VACCINE

Outcome Measures

Primary Outcome Measures :

1. The effectiveness of 2 doses of BNT162b2 (i.e., fully vaccinated) against hospitalization for ARI due to SARS-CoV-2 infection [Time Frame: Dec 2020-Apr 2022]
   VE calculated as 1 minus the odds ratio (OR) comparing the odds of being fully vaccinated (2 doses) with BNT162b2 for hospitalized cases and controls, multiplied by 100%.

Secondary Outcome Measures :

1. The effectiveness of 2 doses of BNT162b2 (i.e., fully vaccinated) against ED admission (without subsequent hospitalization) for ARI due to SARS-CoV-2 infection. [Time Frame: Through study completion, average of one year]
   VE calculated as 1 minus the OR comparing the odds of being fully vaccinated (2 doses) with BNT162b2 for ED cases and controls, multiplied by 100%.
2. The effectiveness of only 1 dose of BNT162b2 (i.e., partially vaccinated) against hospitalization for ARI due to SARS-CoV-2 infection [Time Frame: Through study completion, average of one year]
   VE calculated as 1 minus the OR comparing the odds of being partially vaccinated with BNT162b2 (only 1 dose) for hospitalized cases and controls, multiplied by 100%.
3. The effectiveness of only 1 dose of BNT162b2 (i.e., partially vaccinated) against ED admission (without subsequent hospitalization) for ARI due to SARS-CoV-2 infection. [Time Frame: Through study completion, average of one year]
   VE calculated as 1 minus the OR comparing the odds of being partially vaccinated with BNT162b2 (only 1 dose) for ED cases and controls, multiplied by 100%.
4. The effectiveness of ≥1 dose of BNT162b2 (i.e., ever vaccinated) against hospitalization for ARI due to SARS-CoV-2 infection. [Time Frame: Through study completion, average of one year]
   VE calculated as 1 minus the OR comparing the odds of ever being vaccinated (≥1 dose) with BNT162b2 for hospitalized cases and controls, multiplied by 100%.
5. The effectiveness of ≥1 dose of BNT162b2 (i.e., ever vaccinated) against ED admission (without subsequent hospitalization) for ARI due to SARS-CoV-2 infection. [Time Frame: Through study completion, average of one year]
   VE calculated as 1 minus the OR comparing the odds of ever being vaccinated (≥1 dose) with BNT162b2 for ED cases and controls, multiplied by 100%.
6. The effectiveness of BNT162b2 against hospitalization and ED admission stratified by prevalent or important viral strains [Time Frame: Through study completion, average of one year]
   BNT162b2 VE estimates stratified by virus variant (as determined by genome sequencing) and select descriptive analyses described above
7. The effectiveness of BNT162b2 against severe hospitalization-related outcomes (e.g., ICU admission, mechanical ventilation, and death) [Time Frame: Through study completion, average of one year]
   BNT162b2 VE estimates against severe out-comes including ICU admission, mechanical ventilation, and death

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:	16 Years and older (Child, Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population
All members of KPSC aged greater or equal to 16 years of age.

Criteria
Inclusion Criteria Test Negative Design

- KPSC patients 16 years or older who are admitted to the hospital (primary objective) with acute respiratory infection (ARI) after 14 December 2020 (date of first vaccinations at KPSC), and who receive a PCR test for SARS-CoV-2.
- For secondary objectives estimating VE against ED admission, the TND will include KPSC patients 16 years or older who present to the ED with ARI after 14 December 2020, and who receive a PCR test for SARS-CoV-2.
- Membership requirement of 6 months prior to index date, which is de-fined as the date of hospitalization or ED admission (allowing 31-day administrative gap), to facilitate accurate capture of comorbid conditions.
- Inclusion Criteria Cohort Design
- All KPSC members as of 14 December 2020 (date of first Pfizer vaccination at KPSC) who are age 16 and older.
- Patients must have at least 6 months of membership (allowing 31-day administrative gap) prior to 14 December 2020 (index date, date vaccinations first began at KPSC) to facilitate accurate capture of comorbid conditions.

Exclusion Criteria Test Negative Design • Patients who receive any other newly licensed or investigational SARS-CoV-2 vaccine or COVID-19 prophylactic agent other than Pfizer's COVID-19 vaccine prior to hospitalization (or ED, for secondary objective) will be excluded from the analysis. Patients will also be excluded if the index date is within certain time windows from vaccination date.

Exclusion Criteria Cohort Design

• There will be no exclusion criteria for the cohort design, however patients will be censored for receiving any other newly licensed or investigational SARS-CoV-2 vaccine or COVID-19 prophylactic agent other than Pfizer's COVID-19 vaccine. Patients will also be censored if the event (hospitalization, ED encounter, etc.) occurs within certain time windows from vaccination date.

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): ***NCT04848584***

Locations

United States, California
Pfizer Inc
San Diego, California, United States, 92121

Sponsors and Collaborators
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):

Tartof SY, Slezak JM, Fischer H, Hong V, Ackerson BK, Ranasinghe ON, Frankland TB, Ogun OA, Zamparo JM, Gray S, Valluri SR, Pan K, Angulo FJ, Jodar L, McLaughlin JM. Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study. Lancet. 2021 Oct 16;398(10309):1407-1416. doi: 10.1016/S0140-6736(21)02183-8. Epub 2021 Oct 4.

Responsible Party:	Pfizer
ClinicalTrials.gov Identifier:	NCT04848584 History of Changes
Other Study ID Numbers:	C4591014
First Posted:	April 19, 2021 Key Record Dates
Last Update Posted:	August 11, 2021
Last Verified:	August 2021

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
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.

Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
Product Manufactured in and Exported from the U.S.:	No

Additional relevant MeSH terms:

- COVID-19
- Respiratory Tract Infections
- Infections
- Pneumonia, Viral
- Pneumonia
- Virus Diseases
- Coronavirus Infections
- Coronaviridae Infections
- Nidovirales Infections
- RNA Virus Infections
- Lung Diseases
- Respiratory Tract Diseases
- Vaccines
- Immunologic Factors
- Physiological Effects of Drugs