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Cli	nicalTrials.g	ov						<u> </u>
Home	Search Results >	Study Record Deta	il				Save this st	udy
Pfize	er-BioNTech COVID	-19 BNT162b2	Vaccine Effectiveness St	udy - Kaiser Per	manente Souther	n California		
					ClinicalTrials.gov	dentifier: NCT04	848584	
The safet	y and scientific validity o	f this study is the	responsibility of the study					
-	• •	-	mean it has been evaluated		Recruitment Status 1 : Active, not recruiting First Posted 1 : April 19, 2021			
by the U.	S. Federal Government.	Read our <u>disclaim</u>	<u>er</u> for details.			ted <b>1</b> : August 11	1, 2021	
Sponsor:								
Pfizer								
Information prov	ided by (Responsible Pa	rty):						
Pfizer								
Study Details	Tabular View No	Results Posted	Disclaimer I How to Rea	d a Study Record				
Study Description							Go to 💌	
Brief Summary: The primary object	tive of this study is to det	ermine the vaccine	effectiveness of 2 doses of Pfizer-	BioNTech BNT162b2	vaccine against COVID-	19-associated hos	spitalization. There will be a larg	ne retrospective
	-		ve case-control design and a retros		-			-
	Condition or disease <b>()</b>		Intervention/treatment					
	COVID-19		Biological: Primary Exposure State	us of Pfizer-BioNTech	COVID-19 Vaccine			
Detailed Descriptior	1:							
The primary object	tive of this study is to det	ermine the vaccine	effectiveness (VE) of 2-doses of Pf	fizer's BNT162b2 vaco	cine against COVID-19-	associated hospita	alization. In addition, VE of 1 do	ose and at least one
			alization to be assessed include CC			•		
•			a test-negative case-control design. The retrospective cohort analysis	-	-		. ,	•
			e will further conduct exploratory a	C C	•	on (primary), ico		n, and outpatient
Study Design							Go to 💌	
	Study Type <b>1</b> : O	bservational						
	nated Enrollment <b>()</b> : 99							
(	Observational Model: Ca							
	Time Perspective: Re	·		tivonoco Ctudur Vali	por Dor monorte Cauth	orp California		
	Study Start Date 1 : M		VID-19 BNT162b2 Vaccine Effec	Liveness Sludy - Kals	Ser rer-manemile South			

Estimated Primary Completion Date 1: April 1, 2022

Estimated Study Completion Date 1: July 30, 2023

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

# **Outcome Measures**

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# 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  $\geq 1$  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 ( $\geq 1$  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.

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

• 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

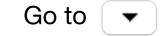
• There will be no exclusion criteria for the cohort design, however patients will be censored for receiving any other newly licensed or investigational SARS-CoV-2 vaccine or COVID-19 prophylactic agent other than Pfizer's COVID-19 vaccine. Patients will also be censored if the event (hospitalization,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

### **Contacts and Locations**

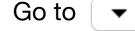
Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT04848584

Information from the National Library of Medicine

**United States, California** 



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# Pfizer Inc

San Diego, California, United States, 92121

### **Sponsors and Collaborators**

Pfizer

# Investigators

Study Director: Pfizer CT.gov Call Center Pfizer

# **More Information**

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

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