

NCICOID

NCI COVID-19 in Cancer Patients Study (NCCAPS): A Longitudinal Natural History Study

ClinicalTrial.gov Identifier: NCT04387656

Study Background

Description

The NCI COVID-19 in Cancer Patients Study, or NCCAPS, is a natural history study of COVID-19 in people with cancer. As part of the study, researchers will collect blood samples, medical information, and medical images from people with cancer who also have COVID-19. Participants will be followed for up to 2 years to help doctors and researchers understand how cancer affects COVID-19 and COVID-19 affects cancer.

To participate in the study, patients must be actively undergoing cancer treatment (chemotherapy, targeted therapy, immunotherapy, and/or radiation therapy) or follow-up care after treatment that requires them to regularly visit a health care facility. Participation in this study will not require additional hospital visits. The study aims to enroll about 2,000 people with cancer and COVID-19 nationwide.

The study will allow researchers to:

- Learn more about the risk factors related to serious illness from COVID-19 in people who are having treatment for cancer
- Study how COVID-19 affects cancer treatment and the results of the treatment

- Find genetic risk factors and markers of serious illness from COVID-19 in people with cancer
- Create a bank of data, blood samples, and images from people with COVID-19 and cancer for future research

Study Milestones:

Start date: May 2020

Publication Information:

Analysis Type: Primary

PubMed ID: 36702472

Citation: Ana F Best, PhD, Melissa Bowman, MS, Jessica Li, MPH, Grace E Mishkin, MPH, PhD, Andrea Denicoff, RN, MS, Marwa Shekfeh, PhD, Larry Rubinstein, PhD, Jeremy L Warner, MD, MS, Brian Rini, MD, Larissa A Korde, MD, MPH, COVID-19 severity by vaccination status in the NCI COVID-19 and Cancer Patients Study (NCCAPS), JNCI: Journal of the National Cancer Institute, 2023;, djad015, <https://doi.org/10.1093/jnci/djad015>

Associated Datasets: NCT04387656-D1-Dataset.csv

Dataset Information:

Dataset Name: NCT04387656-D1-Dataset.csv

Description: This dataset contains information used in the analyses described and presented in “*COVID-19 severity by vaccination status in patients enrolled to the National Cancer Institute COVID-19 and Cancer Patients Study (NCCAPS)*”, including the erratum published on [date].

Data can be used to approximate published study findings, but exact reproduction of the manuscript is not possible due to de-identification procedures. Data presented in Figure 1 in the publication are not contained within this data submission, and data presented in Figure 2 have been modified due to de-identification procedures. Specifically, dates of study enrollment and first positive SARS-CoV-2 test have been omitted and year of first positive SARS-CoV-2 test has been substituted for time period of first positive SARS-CoV-2 test.

As described in the protocol, patients who did not receive active anticancer treatment within six weeks of enrollment or did not have a history of stem cell transplant or CAR-T cell therapy were considered eligible if they were anticipated to receive such treatment within two weeks of their positive COVID test.

NCT04387656-D1-Dataset.csv Data Dictionary:

Field Identifier	Field Name	Values	Description
ID_public	Patient ID	Text, length 12	Patient ID
year_test	Year of first positive SARS-CoV-2 test	2020, 2021, 2022	Year of the patient's first positive SARS-CoV-2 antigen test (referred to in future fields as "first positive test"). The month and day have been redacted for de-identification purposes.
age_cat	Age of patient at enrollment	18-39, 40-64, 65+	Patient age in years on date of study enrollment 18-39: Patient age at enrollment was at least 18 years and less than 40 years. 40-64: Patient age at enrollment was at least 40 years and less than 65 years. 65+: Patient age at enrollment was at least 65 years.
sex	Sex	F, M	Patient biological sex F: Female M: Male
race_ethnicity	Race/Ethnicity	NHW, NHB, H, OTH, UNK	Combination of self-reported patient race and ethnicity NHW: Non-Hispanic white, NHB: Non-Hispanic black or African American, H: Hispanic or Latino, OTH: Other UNK: Unknown or unspecified The category "Other" includes Asian/Pacific Islander, American Indian/Alaskan Native, other.

			<p>The category “Hispanic” includes patients whose ethnicity was Hispanic or Latino regardless of the race value.</p> <p>The category “Unknown or unspecified” includes patients whose ethnicity was Unknown or Not Reported or whose race value was Unknown or Not Reported (except as noted for category ‘Hispanic’).</p> <p>No patients who enrolled in the study self-identified as two or more race categories.</p>
baseline_vax_clean	Baseline Vaccination Status	Fully Vaccinated, Not Fully Vaccinated, NA	<p>Patient’s vaccination status at time of first positive SARS CoV-2 test date.</p> <p>“Fully Vaccinated”: the patient’s first positive test was 2 weeks after either their second dose of mRNA vaccine (BNT162b2 or mRNA-1273) or a single dose of adenovirus vector vaccine (Ad26.COV2.S).</p> <p>“Not Fully Vaccinated”: the patient’s first positive test occurred prior to qualifying as fully vaccinated (received only 1 dose of the 2-dose regimen or the test was less than 2 weeks after the last dose described above), or the vaccination occurred after the test date. This category also includes patients whose vaccination status is unknown and whose first positive test occurred prior to February 1, 2021, based on the initial limited availability of the vaccine.</p> <p>NA: the patient’s vaccination status is unknown and their first positive test date is after February 1, 2021.</p>

severity_30d	30-Day Severity	N, Y	Indicates the patient's death or hospitalization for COVID-19 treatment within 30 days of their first positive test. Y (Yes): The patient had a severe outcome, defined as death or hospitalization for COVID-19 treatment within 30 days of their first positive test. N (No): The patient did not have a severe outcome as defined above.
disease_cat	Category of Malignancy	Acute Leukemia, Lung, Lymphoma, Other Heme, Solid Met, Solid Non-Met	Category of patient's malignancy type and malignancy status. Acute Leukemia: acute leukemia, any type Lung: lung cancer (metastatic or nonmetastatic at enrollment) Lymphoma: lymphoma, any type Other Heme: Other hematologic malignancy; includes chronic leukemias, multiple myeloma, and myelodysplastic syndromes Solid Met: Non-lung solid tumor, metastatic at enrollment Solid Non-Met: Non-lung solid tumor, not metastatic at enrollment
type2_diabetes	Type 2 Diabetes	N, Y, NA	Type 2 Diabetes status from the patient's baseline medical history Y (Yes): patient's baseline medical history indicates they had type 2 diabetes at enrollment. N (No): patient's baseline medical history indicates they did not have type 2 diabetes at enrollment. NA: patient's type 2 diabetes status is missing from their baseline medical history
anticoagulation	Anticoagulation Meds	N, Y	Indicates if patient was receiving 1 or more anticoagulant medications on the date of their first positive test. Y: Yes N: No
BMI_cat	BMI Category	Normal, Obese,	Patient's BMI (body mass index, measured in kg/m ²) category at enrollment

		Overweight, Underweight, NA	Normal: patient BMI at enrollment was equal to or greater than 18.5 and less than 25 (18.5 <= BMI < 25) Obese: patient BMI at enrollment was equal or greater to 30 (BMI >= 30) Overweight: patient BMI at enrollment was equal to or greater than 25 and less than 30 (25 <= BMI < 30) Underweight: patient BMI at enrollment was less than 18.5 (BMI < 18.5) NA: patient height and/or weight values at enrollment were missing
Chemo	Chemotherapy	TRUE, FALSE	Indicates if patient received 1 or more chemotherapy drugs for cancer treatment during the 6 weeks prior to the first positive test date. TRUE: patient received one or more chemotherapy drugs for cancer treatment during the six weeks prior to their first positive test date FALSE: patient did not receive any drugs of this type during this time period
CPI	Immune Checkpoint Inhibitor	TRUE, FALSE	Indicates if patient received 1 or more immune checkpoint inhibitor drugs for cancer treatment during the 6 weeks prior to the first positive test date. TRUE: patient received one or more immune checkpoint inhibitor drugs for cancer treatment during the six weeks prior to their first positive test date FALSE: patient did not receive any drugs of this type during this time period
Targeted_Heme	Targeted Treatment for Hematologic Malignancies	TRUE, FALSE	Indicates if patient received 1 or more targeted treatments for hematologic cancers during the 6 weeks prior to the first positive test date. TRUE: patient received one or targeted treatments for a hematologic cancer during the six weeks prior to their first positive test date FALSE: patient did not receive any treatments of this type during this time period

Targeted_Solid	Targeted Treatment for Solid Tumors	TRUE, FALSE	Indicates if patient received 1 or more targeted treatments for solid tumor cancers during the 6 weeks prior to the first positive test date. TRUE: patient received one or more targeted treatments for a solid tumor cancer during the six weeks prior to their first positive test date FALSE: patient did not receive any treatments of this type during this time period
Transplant	Stem Cell Transplant or CAR-T	TRUE, FALSE	Indicates if patient received a stem cell transplant or CAR-T therapy at any point prior to the first positive test date. TRUE: patient received a stem cell transplant or CAR-T therapy at any point prior to their first positive test date FALSE: patient did not receive any treatments of this type during this time period
Radiation	Radiation	TRUE, FALSE	Indicates if patient received any radiotherapy for cancer treatment during the 6 weeks prior to the first positive test date. TRUE: patient received radiotherapy for cancer treatment during the six weeks prior to their first positive test date FALSE: patient did not receive any treatments of this type during this time period
Experimental	Experimental	TRUE, FALSE	Indicates if patient received experimental agents (e.g., clinical trials) for cancer treatment during the 6 weeks prior to the first positive test date. TRUE: patient received one or more experimental agents for cancer treatment during the six weeks prior to their first positive test date FALSE: patient did not receive any treatments of this type during this time period
OtherCancerTrx	Other Cancer Treatment	TRUE, FALSE	Indicates if patient received other therapies for cancer treatment during the 6 weeks prior to the first positive test date. Other therapies include endocrine therapy, local therapies (i.e. intrathecal, intrahepatic, intralesional), hydroxyurea, octreotide, BCG, and radionuclide therapies

			<p>TRUE: patient received one or more other therapies as defined above for cancer treatment during the six weeks prior to their first positive test date</p> <p>FALSE: patient did not receive any treatments of this type during this time period</p>
MonoclonalAB	Monoclonal Antibody Treatment	TRUE, FALSE	<p>Indicates if patient received monoclonal antibodies for treatment of COVID-19 within 30 days of the first positive test date.</p> <p>TRUE: patient received monoclonal antibodies for COVID-19 treatment within 30 days of their first positive test date</p> <p>FALSE: patient did not receive any treatments of this type during this time period</p>
ConvPlasma	Convalescent Plasma Treatment	TRUE, FALSE	<p>Indicates if patient received convalescent plasma for treatment of COVID-19 within 30 days of the first positive test date.</p> <p>TRUE: patient received convalescent plasma for COVID-19 treatment within 30 days of their first positive test date</p> <p>FALSE: patient did not receive any treatments of this type during this time period</p>
Antiviral	Antiviral Treatment	TRUE, FALSE	<p>Indicates if patient received antiviral medications for treatment of COVID-19 within 30 days of the first positive SARS CoV-2 test date.</p> <p>TRUE: patient received one or more antiviral medications for COVID-19 treatment within 30 days of their first positive test date</p> <p>FALSE: patient did not receive any treatments of this type during this time period</p>
OtherC19Trx	Other COVID-19 Treatment	TRUE, FALSE	<p>Indicates if patient received other covid treatments for treatment of COVID-19 within 30 days of the first positive SARS CoV-2 test date. Includes tocilizumab and baricitinib; does not include hydroxychloroquine or ivermectin.</p> <p>TRUE: patient received one or more other therapies as defined above for COVID-19</p>

			treatment within 30 days of their first positive test date FALSE: patient did not receive any treatments of this type during this time period
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