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

Status: Completed

Eligibility Criteria

Sex: All
Age: Not specified
This study is NOT accepting healthy volunteers

Inclusion Criteria:

• NCCAPS STUDY ELIGIBILITY CRITERIA:

• Patient must have a prior or current cancer diagnosis (e.g., solid tumor or hematologic malignancy) and cancer treatment that fits into one of the three following categories:

• Metastatic (stage IV) solid tumor, any hematologic malignancy, or any central nervous system (CNS) malignancy, and:

• Patient is receiving eligible active treatment (defined as current treatment or treatment within the 6 weeks prior to their first positive SARS-CoV-2 test collection) or is expected to begin receiving treatment within 2 weeks of study enrollment

• Eligible active treatment types are chemotherapy, immunotherapy, monoclonal antibody therapy (e.g., rituximab, trastuzumab, cetuximab), targeted therapy (e.g., BRAF/MEK inhibitor, EGF-R inhibitor), endocrine therapy, radiation therapy, or targeted radionuclide therapy; OR

• Non-metastatic (Stage I-III) solid tumor and:

• Patient is receiving eligible active treatment (defined as current treatment or treatment within past 6 weeks prior to their first positive SARS-CoV-2 test collection) or is expected to begin receiving treatment within 2 weeks of study enrollment

• Eligible active treatment types for non-metastatic solid tumor patients are intravenous chemotherapy, immunotherapy, targeted therapy, radiation therapy, targeted radionuclide therapy, or monoclonal antibody therapy (except as noted below)

• HER2-targeted therapy (trastuzumab, pertuzumab, neratinib, ado-trastuzumab) that is not accompanied by chemotherapy is NOT considered an eligible active treatment

• Patients on endocrine therapy alone are not eligible; OR

• Prior or current transplant for the treatment of cancer:

• Patient has received an allogenic stem cell/bone marrow transplant or chimeric antigen receptor (CAR)-T cell or other modified cellular therapy at any time; or

• Patient is currently receiving treatment or prophylaxis for graft graft versus (vs.) host disease; or

• Patient has received an autologous stem cell/bone marrow transplant within the past 2 years

• Patient must have documented positive viral test result for SARS-CoV-2

• For patients 18 years of age or older, the specimen collection for the patient's FIRST positive test must have occurred no earlier than 14 days prior to enrollment

• For patients under 18 years of age, the specimen collection for the patient's first positive test must have occurred after January 31, 2020

• The viral test can be either a nucleic acid (PCR) test or an antigen test. Serological or antibody tests are not allowed

• Any specimen source (e.g., nasopharyngeal swab, oropharyngeal swab, etc.) is allowable for the viral SARS-CoV-2 test

• Patients with prior negative viral SARS-CoV-2 test(s) are eligible if they are being tested again

• The SARS-CoV-2 test must be a validated diagnostic assay performed in accordance with the most recent guidance issued by the FDA in the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency. This policy is available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-c oronavirus-disease-2019-tests-during-public-health-emergency-revised

• Human immunodeficiency virus (HIV)-infected patients are eligible

• Patients with CNS metastases are eligible

• Co-enrollment on other clinical trials (for cancer or for COVID-19) is allowed

• PEDIATRIC COVNET COHORT ELIGIBILITY CRITERIA: Patients should only be enrolled in the pediatric COVNET cohort if they are not eligible for the main NCCAPS Study cohort or decline to participate in the main study

• Patient must be < 18 years of age

• Patient must have a positive SARS-CoV-2 viral test after January 31, 2020

• Patient must have a current or prior diagnosis of cancer. Active cancer treatment is not required

• Note: Patients who enroll on Pediatric COVNET cohort will not be followed longitudinally; study data collection involves only a single questionnaire and research blood collection. A separate consent document is provided for the Pediatric COVNET cohort

Conditions & Interventions

Interventions:
Procedure: Biospecimen Collection, Other: Data Collection, Other: Quality-of-Life Assessment, Other: Questionnaire Administration
Conditions:
COVID-19 Infection, Hematopoietic and Lymphoid Cell Neoplasm, Malignant Solid Neoplasm, Metastatic Malignant Solid Neoplasm
Keywords:
COVID-19, Clinics and Surgery Center (CSC)

More Information

Description: -Characterize patient factors, such as pre-existing comorbidities, cancer type and treatment, and demographic factors, associated with short- and long-term outcomes of COVID-19, including severity and fatality, in cancer patients undergoing treatment. -Describe cancer treatment modifications made in response to COVID-19, including dose adjustments, changes in symptom management, or temporary or permanent cessation. -Evaluate the association of COVID-19 with cancer outcomes in patient subgroups defined by clinico-pathologic characteristics.
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Phase: NA
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