A Study Using Nivolumab, in Combination With Chemotherapy Drugs to Treat Nasopharyngeal Carcinoma (NPC)

Status: RECRUITING

Eligibility Criteria

Age: Up to 21 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients must be ≤ 21 years of age at the time of study enrollment * Newly diagnosed American Joint Committee on Cancer (AJCC) stage II-IV nasopharyngeal carcinoma (NPC) * Patients must have had histologic verification of the malignancy at original diagnosis * Although submission of tumor tissue for the molecular characterization initiative is not required for eligibility, it is strongly recommended * Patients must have had histologic verification of the malignancy at original diagnosis * Although submission of tumor tissue for the molecular characterization initiative is not required for eligibility, it is strongly recommended * Patients must have a Lansky (for patients ≤ 16 years of age) or Karnofsky (for patients \> 16 years of age) performance status score of ≥ 60% * Peripheral absolute neutrophil count (ANC) ≥ 1000/uL (within 7 days prior to start of protocol therapy) * Platelet count ≥ 100,000/uL (transfusion independent) (within 7 days prior to start of protocol therapy) * Creatinine clearance or radioisotope glomerular filtration rate (GFR) ≥ 60 mL/min/1.73 m\^2 or (within 7 days prior to start of protocol therapy) * A serum creatinine based on age/sex (within 7 days prior to start of protocol therapy) Age: Maximum serum creatinine (mg/dL) 1 month to \< 6 months: 0.4 mg/dL (male); 0.4 mg/dL (female) 6 months to \< 1 year: 0.5 mg/dL (male); 0.5 mg/dL (female) 1 to \< 2 years: 0.6 mg/dL (male); 0.6 mg/dL (female) 2 to \< 6 years: 0.8 mg/dL (male); 0.8 mg/dL (female) 6 to \< 10 years 1 mg/dL (male); 1 mg/dL (female) 10 to \<13 years: 1.2 mg/dL (male); 1.2 mg/dL (female) 13 to \< 16 years: 1.5 mg/dL (male); 1.4 mg/dL (female) ≥ 16 years: 1.7 mg/dL (male); 1.4 mg/dL (female) * Total bilirubin ≤ 1.5 x upper limit of normal (ULN) for age, and (within 7 days prior to start of protocol therapy) * Serum glutamic-pyruvic transaminase (SGPT) (alanine aminotransferase \[ALT\]) ≤ 135 U/L* (within 7 days prior to start of protocol therapy) * Note: For the purpose of this study, the ULN for SGPT (ALT) has been set to the value of 45 U/L * Shortening fraction of ≥ 27% by echocardiogram, or * Ejection fraction of ≥ 50% by radionuclide angiogram * No evidence of dyspnea at rest, no exercise intolerance, and a pulse oximetry \> 94% if there is clinical indication for determination * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months and T-cell count above the lower limit of normal are eligible for this trial * For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated. Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load

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Exclusion Criteria:

* Patients who received prior radiotherapy to the head or neck * Patients who received prior chemotherapy or radiation for the treatment of any cancer in the last 3 years. These patients must also be in remission * Patients with a diagnosis of immunodeficiency * Patients with an active autoimmune disease that has required systemic treatment in the past 2 years (i.e., with use of disease-modifying agents, corticosteroids, or immunosuppressive agents). Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency, etc.) is not considered a form of systemic treatment. * Note: Patients with well-controlled asthma and no need for systemic steroids for the treatment of asthma in the last 12 months will not be excluded * Patients with a condition requiring systemic treatment with either corticosteroids (\> 0.25 mg/kg (10 mg) daily prednisone equivalent) within 14 days or other immunosuppressive medications within 30 days of enrollment. Inhaled or topical steroids, and adrenal replacement steroid doses \> 0.25 mg/kg (10 mg) daily prednisone equivalent, are permitted in the absence of active autoimmune disease * Patients with a history of (non-infectious) pneumonitis that required steroids or current pneumonitis * Patients with detectable viral load of human immunodeficiency virus (HIV), hepatitis B or hepatitis C, or active tuberculosis * Patients who have undergone solid organ or allogeneic hematopoietic transplant at any time * Due to risks of fetal and teratogenic adverse events as seen in animal studies, a negative pregnancy test must be obtained in females of childbearing potential, defined as females who are post-menarchal. If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test will be required * Females of childbearing potential that are sexually active must agree to either practice 2 medically accepted highly-effective methods of contraception at the same time or abstain from heterosexual intercourse from the time of signing the informed consent through 5 months after the last dose of nivolumab, 6 months after the last dose of gemcitabine, and 14 months after the last dose of cisplatin, whichever is longer * Males of childbearing potential that are sexually active must agree to either practice a medically accepted highly-effective methods of contraception or abstain from heterosexual intercourse from the time of signing the informed consent through 3 months after the last dose of gemcitabine, and 11 months after the last dose of cisplatin, whichever is longer * Lactating females are not eligible unless they have agreed not to breastfeed their infants starting with the first dose of study therapy through 5 months after the last dose of nivolumab * All patients and/or their parents or legal guardians must sign a written informed consent * All institutional, Food and Drug Administration (FDA), and National Cancer Institute (NCI) requirements for human studies must be met

Conditions & Interventions

Interventions:

PROCEDURE: Biopsy Procedure, PROCEDURE: Biospecimen Collection, PROCEDURE: Chest Radiography, DRUG: Cisplatin, PROCEDURE: Computed Tomography, PROCEDURE: Echocardiography Test, OTHER: Electronic Health Record Review, OTHER: Fluciclovine F18, DRUG: Gemcitabine, PROCEDURE: Magnetic Resonance Imaging, PROCEDURE: Multigated Acquisition Scan, BIOLOGICAL: Nivolumab, PROCEDURE: Positron Emission Tomography, OTHER: Quality-of-Life Assessment, OTHER: Questionnaire Administration, RADIATION: Radiation Therapy, PROCEDURE: X-Ray Imaging

Conditions:

Stage II Nasopharyngeal Carcinoma AJCC v8, Stage III Nasopharyngeal Carcinoma AJCC v8, Stage IV Nasopharyngeal Carcinoma AJCC v8

More Information

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Principal Investigator:

Phase: PHASE2

IRB

Number:

System ID: NCT06064097
