

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

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: Up to 21 years old

Healthy Volunteers: This study is NOT accepting healthy 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
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- Patients must have a Lansky (for patients ≤ 16 years of age) or Karnofsky (for patients > 16 years of age) performance status score of $\geq 60\%$
- Peripheral absolute neutrophil count (ANC) $\geq 1000/\mu\text{L}$ (within 7 days prior to start of protocol therapy)
- Platelet count $\geq 100,000/\mu\text{L}$ (transfusion independent) (within 7 days prior to start of protocol therapy)
- Creatinine clearance or radioisotope glomerular filtration rate (GFR) $\geq 60 \text{ mL/min/1.73 m}^2$ 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 $\leq 1.5 \times$ 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]) $\leq 135 \text{ U/L}^*$ (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 $\geq 27\%$ by echocardiogram, or
 - Ejection fraction of $\geq 50\%$ 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

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 ($> 0.25 \text{ mg/kg}$ (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 $> 0.25 \text{ mg/kg}$ (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

Description:

This phase II trial tests effects of nivolumab in combination with chemotherapy drugs prior to radiation therapy patients with nasopharyngeal carcinoma (NPC). Immunotherapy with monoclonal antibodies, such as nivolumab, may help the body's immune system attack the cancer, and may interfere with the ability of tumor cells to grow and spread. Chemotherapy drugs, such as gemcitabine and cisplatin, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Radiation therapy uses high energy x-rays, particles, or radioactive seeds to kill cancer cells and shrink tumors. Researchers want to find out what effects, good and/or bad, adding nivolumab to chemotherapy has on patients with newly diagnosed NPC. In addition, they want to find out if children with NPC may be treated with less radiation therapy and whether this decreases the side effects of therapy.

Contact(s): - cancer@cchmc.org

Principal Investigator:

Principal Investigator ID:

Phase: PHASE2

IRB Number:

System ID: NCT06064097

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