Induction Pembrolizumab and Chemotherapy Followed by Pembrolizumab Before Chemoradiation and Pembrolizumab Maintenance Compared to Standard Chemoradiation With Pembrolizumab Followed by Pembrolizumab Maintenance in High-Risk Cervical Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients must have pathologically confirmed newly diagnosed cervical cancer. Eligible pathologic types: squamous cell carcinoma, adenocarcinoma, adenosquamous cell carcinoma * Patients must have locally advanced cervical cancer (LACC) with T3 or T4 disease with or without lymph node involvement: * IIIA (T3aN0M0) * IIIB (T3bN0M0) * IIIC1(T3aN1M0, T3bN1M0) * IIIC2 (T3aN2M0, T3bN2M0) * IVA (T4aN0M0, T4aN1M0, T4aN2M0) No prior hysterectomy defined as removal of the entire uterus. * NOTE: prior partial/subtotal hysterectomy for reasons other than cervical cancer are eligible to participate in the study. No plan to perform a hysterectomy as part of initial cervical cancer therapy. No paraaortic lymph node (PALN) metastases above the T12/L1 interspace. * Note: Nodal status can be confirmed by imaging (CT, MRI, or PET/CT), fine needle aspirate/core biopsy, extra peritoneal biopsy, laparoscopic biopsy, or lymphadenectomy. Radiologic definition of lymph node staging: * N1: ' One or more pelvic lymph nodes with short axis diameter of ≥ 15 mm (axial plane) by CT or MRI, and/or * One or more pelvic lymph nodes with short axis diameter of ≥ 10 mm and standardized uptake value maximum (SUVmax) ≥ 2.5 by fludeoxyglucose (FDG)-PET * N2: * One or more para-aortic lymph node with short axis diameter of ≥ 15 mm (axial plane) by CT or MRI, and/or * One or more para-aortic lymph node with short axis diameter of ≥ 10 mm and SUVmax ≥ 2.5 by FDG-PET * No prior definitive surgical, radiation, or systemic therapy for cervical cancer * No prior immunotherapy * No prior pelvic radiation therapy for any disease * Age ≥ 18 * Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 2 * Not pregnant and not nursing * Absolute neutrophil count (ANC) ≥ 1,500 cells/mm\^3 * Platelets ≥ 100,000 cells/mm\^3 * Hemoglobin ≥ 8 g/dl (Note: The use of transfusion or other intervention to achieve hemoglobulin \[Hgb\] ≥ 8 g/dl is acceptable) * Creatinine clearance (CrCL) of ≥ 50 mL/min by the Cockcroft-Gault formula * Total bilirubin ≤ 1.5 x institutional upper limit of normal (ULN) (patients with known Gilbert's disease who have bilirubin level ≤ 3 x institutional ULN may be enrolled) * Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) ≤ 3 x institutional ULN * Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class 2B or better * No active infection requiring parenteral antibiotics * No live vaccine within 30 days prior to registration. Examples of live vaccines include, but are not limited to, the following: measles, mumps, rubella, varicella/zoster (chicken pox), yellow fever, rabies, Bacille Calmette Guerin (BCG), and typhoid vaccine. Seasonal influenza vaccines for injection are generally killed virus vaccines and are allowed; however, intranasal influenza vaccines are live attenuated vaccines and are not allowed * No diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy (in dosing exceeding 10 mg daily of prednisone equivalent) or any other form of immunosuppressive therapy within 7 days prior registration * No active autoimmune disease that has required systemic treatment in past 2 years (i.e., with use of disease modifying agents, corticosteroids or immunosuppressive drugs). Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency) is not considered a form of systemic treatment and is allowed * No history of (non-infectious) pneumonitis that required steroids, or current pneumonitis * No history of allergic reaction to the study agent(s) or compounds of similar chemical or biologic composition to the study agent(s) (or any of its excipients)

Conditions & Interventions

Interventions:
PROCEDURE: Biospecimen Collection, RADIATION: Brachytherapy, DRUG: Carboplatin, PROCEDURE: Chest Radiography, DRUG: Cisplatin, PROCEDURE: Computed Tomography, RADIATION: External Beam Radiation Therapy, RADIATION: Intensity-Modulated Radiation Therapy, PROCEDURE: Magnetic Resonance Imaging, DRUG: Paclitaxel, BIOLOGICAL: Pembrolizumab, PROCEDURE: Positron Emission Tomography

Conditions:
Locally Advanced Cervical Adenocarcinoma, Locally Advanced Cervical Adenosquamous Carcinoma, Locally Advanced Cervical Squamous Cell Carcinoma, Stage IIIA Cervical Cancer FIGO 2018, Stage IIIB Cervical Cancer FIGO 2018, Stage IIIC1 Cervical Cancer FIGO 2018, Stage IIIC2 Cervical Cancer FIGO 2018, Stage IVA Cervical Cancer FIGO 2018

More Information

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